

DEPARTMENT OF HEALTH

SUBJECT: Rules for Critical Access Hospitals in Arkansas, 20 CAR pt. 43

DESCRIPTION: The proposed amendments to the Rules for Critical Access Hospitals in Arkansas are pursuant to Acts 52, 138, 141, 772, 819, 861, and 862 of 2025 which include: allowing full practice authority of certified midwives, permitting hospitals to operate retail pharmacies, adding provisions for emergent blood transfusion process, allowing APRNs to pronounce and document patient death, and requirement to End Organ and Genomic Harvesting, and amending the Anatomical Gift Act.

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired on August 4, 2026. The agency indicated that it received no comments.

The proposed effective date is October 1, 2026.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

LEGAL AUTHORIZATION: The Department of Health, Division of Health Facilities Services has the authority to inspect, regulate, and license hospitals and institutions. Ark. Code Ann. § 20-9-204(b)(3). The Department may promulgate rules as necessary to accomplish the purposes of Ark. Code Ann. §§ 20-9-201 to -223, regarding health facilities services. Ark. Code Ann. § 20-9-205(b). This rule implements Acts 52, 138, 141, 772, 819, 861, and 862 of 2025.

Act 52, sponsored by Senator Jonathan Dismang, removed the prohibition on nonprofit, tax exempt, or governmentally funded hospitals holding a licensed pharmacy permit for the sale at retail of drugs.

Act 138, sponsored by Representative Mary Bentley, amended the full practice authority of a certified nurse midwife to allow admitting privileges.

Act 141, sponsored by Senator Justin Boyd, permitted healthcare providers to maintain medical records in an electronic format.

Act 772, sponsored by Senator Clint Penzo, created the End Organ and Genomic Harvesting Act, prohibited coverage of certain human organ transplant or post-transplant care, and prohibited certain genetic sequencers and genetic analysis technologies.

Act 819, sponsored by Representative Matt Brown, amended the law regarding emotional support animals, authorized a private property owner or business owner to ban an emotional support animal from the private property or the business premises, and regulated liability on private property related to emotional support animals.

Act 861, also sponsored by Representative Brown, amended the Revised Arkansas Anatomical Gift Act, allowed certain classes of persons to revoke or amend an

anatomical gift upon the death of the donor, and required certain reporting of procurement organizations.

Act 862, sponsored by Representative Paul Childress, amended the law concerning death certificates and clarified the medical professionals who may sign a medical certificate of death and pronounce death of a patient.



Sarah Huckabee Sanders
GOVERNOR

Renee Mallory, RN, BSN
SECRETARY OF HEALTH

Jennifer Dillaha, MD
DIRECTOR

To: Members, Arkansas State Board of Health

From: Paula Day, Section Chief
Health Systems Licensing and Regulation
Division for Health Protection

Date: October 11, 2025

Subject: To request approval by the State Board of Health of the following proposed amendments to the Rules for Critical Access Hospitals in Arkansas.

Authority: Ark. Code Ann. §§ 20-7-123, 20-9-201, et seq.

Relevant Acts: Acts 52, 138, 141, 387, 772, 819, 861, and 862 of 2025

20 CAR § 43-104 Governing Body

- Act 138 – Allow full practice authority of certified nurse midwife (page 12)

20 CAR § 43-105 Medical Staff

- Act 861 – Amend anatomical gift act to allow next of kin to modify, amend or revoke (page 20)

20 CAR § 43-106 General Administration

- Act 819 – Allow facility to ban emotional support animals (page 21)
- Act 862 – Provision for advanced practice registered nurse to pronounce and document patient death (page 27)
- Correct ACA reference for attacking a healthcare worker (page 28)
- Act 772 – Add requirements regarding End Organ and Genomic Harvesting (pages 28-29)

20 CAR § 43-113 Health Information Services

- Act 141 – permits providers to maintain medical records in electronic format (pages 46-47)
- Add requirement for hospitals that closes to notify Health Facility Services of the entity that will maintain medical records (page 49)

20 CAR § 43-115 Pharmacy

- Act 52 – permits hospitals to operate a retail pharmacy (page 79)

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- Add requirement for hospital to have policy and procedure outlining the handling of patient abandoned controlled substances. (page 79)

20 CAR § 43-129 Specialized Services – Labor, delivery, labor delivery recovery (LDR), labor delivery recovery postpartum (LDRP), postpartum, and maternal-child education

- Act 138 – Notification of certified nurse midwife for a patient needing evaluation for labor. (page 163)

20 CAR § 43-135 Specialized Services – Emergency Services

- Add provision for emergent blood transfusion process (page 181)

**QUESTIONNAIRE FOR FILING PROPOSED RULES WITH
THE ARKANSAS LEGISLATIVE COUNCIL**

DEPARTMENT _____
BOARD/COMMISSION _____
BOARD/COMMISSION DIRECTOR _____
CONTACT PERSON _____
ADDRESS _____
PHONE NO. _____ EMAIL _____
NAME OF PRESENTER(S) AT SUBCOMMITTEE MEETING _____
PRESENTER EMAIL(S) _____

INSTRUCTIONS

In order to file a proposed rule for legislative review and approval, please submit this Legislative Questionnaire and Financial Impact Statement, and attach (1) a summary of the rule, describing what the rule does, the rule changes being proposed, and the reason for those changes; (2) both a markup and clean copy of the rule; and (3) all documents required by the Questionnaire.

If the rule is being filed for permanent promulgation, please email these items to the attention of Rebecca Miller-Rice, miller-ricer@blr.arkansas.gov, for submission to the Administrative Rules Subcommittee.

If the rule is being filed for emergency promulgation, please email these items to the attention of Director Marty Garrity, garritym@blr.arkansas.gov, for submission to the Executive Subcommittee.

Please answer each question completely using layman terms.

1. What is the official title of this rule?

2. What is the subject of the proposed rule? _____
3. Is this rule being filed under the emergency provisions of the Arkansas Administrative Procedure Act? Yes No

If yes, please attach the statement required by Ark. Code Ann. § 25-15-204(c)(1).

If yes, will this emergency rule be promulgated under the permanent provisions of the Arkansas Administrative Procedure Act? Yes No

4. Is this rule being filed for permanent promulgation? Yes No

If yes, was this rule previously reviewed and approved under the emergency provisions of the Arkansas Administrative Procedure Act? Yes No

If yes, what was the effective date of the emergency rule? _____

On what date does the emergency rule expire? _____

5. Is this rule required to comply with a *federal* statute, rule, or regulation? Yes No

If yes, please provide the federal statute, rule, and/or regulation citation.

6. Is this rule required to comply with a *state* statute or rule? Yes No

If yes, please provide the state statute and/or rule citation.

7. Are two (2) rules being repealed in accord with Executive Order 23-02? Yes No

If yes, please list the rules being repealed.

If no, please explain.

8. Is this a new rule? Yes No

Does this repeal an existing rule? Yes No

If yes, the proposed repeal should be designated by strikethrough. If it is being replaced with a new rule, please attach both the proposed rule to be repealed and the replacement rule.

Is this an amendment to an existing rule? Yes No

If yes, all changes should be indicated by strikethrough and underline. In addition, please be sure to label the markup copy clearly as the markup.

9. What is the state law that grants the agency its rulemaking authority for the proposed rule, outside of the Arkansas Administrative Procedure Act? Please provide the specific Arkansas Code citation(s), including subsection(s).

10. Is the proposed rule the result of any recent legislation by the Arkansas General Assembly?
Yes No

If yes, please provide the year of the act(s) and act number(s).

11. What is the reason for this proposed rule? Why is it necessary?

12. Please provide the web address by which the proposed rule can be accessed by the public as provided in Ark. Code Ann. § 25-19-108(b)(1).

13. Will a public hearing be held on this proposed rule? Yes No

If yes, please complete the following:

Date: _____

Time: _____

Place: _____

Please be sure to advise Bureau Staff if this information changes for any reason.

14. On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date. _____

15. What is the proposed effective date for this rule? _____

16. Please attach (1) a copy of the notice required under Ark. Code Ann. § 25-15-204(a)(1) and (2) proof of the publication of that notice.

17. Please attach proof of filing the rule with the Secretary of State, as required by Ark. Code Ann. § 25-15-204(e)(1)(A).

18. Please give the names of persons, groups, or organizations that you anticipate will comment on these rules. Please also provide their position (for or against), if known.

19. Is the rule expected to be controversial? Yes No

If yes, please explain.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT _____
BOARD/COMMISSION _____
PERSON COMPLETING THIS STATEMENT _____
TELEPHONE NO. _____ **EMAIL** _____

To comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and email it with the questionnaire, summary, markup and clean copy of the rule, and other documents. Please attach additional pages, if necessary.

TITLE OF THIS RULE _____

1. Does this proposed, amended, or repealed rule have a financial impact?
Yes No

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?
Yes No

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes No

If no, please explain:

(a) how the additional benefits of the more costly rule justify its additional cost;

(b) the reason for adoption of the more costly rule;

(c) whether the reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and

(d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.

4. If the purpose of this rule is to implement a *federal* rule or regulation, please state the following:
(a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____

Total _____

Next Fiscal Year

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____

Total _____

(b) What is the additional cost of the state rule?

Current Fiscal Year

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____

Total _____

Next Fiscal Year

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____

Total _____

5. What is the total estimated cost by fiscal year to any private individual, private entity, or private business subject to the proposed, amended, or repealed rule? Please identify those subject to the rule, and explain how they are affected.

Current Fiscal Year

\$ _____

Next Fiscal Year

\$ _____

6. What is the total estimated cost by fiscal year to a state, county, or municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year

\$ _____

Next Fiscal Year

\$ _____

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes No

If yes, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and
 - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
 - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

NOTICE OF PUBLIC COMMENT PERIOD

The Arkansas Department of Health (ADH) is accepting public comments on the **Rules for Critical Access Hospitals in Arkansas, 20 CAR Pt. 43** from July 5, 2026 to August 4, 2026. The comment period is provided to allow interested parties and the public to provide any comments. “The proposed changes update the rule to current requirements regarding Governing Body, Medical Staff, General Administration, Health Information Management, Pharmacy, Labor/Delivery, and Emergency Services.” The proposed rule revision with a summary of changes can be viewed online at <https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules> or you may request a copy from our office at 501-661-2201.

Comments on the proposed changes can also be mailed to Comments, Arkansas Department of Health, Section of Health Facilities Services, Freeway Medical Tower, 5800 West Tenth Street, Suite 400, Little Rock, Arkansas 72204, or emailed to paula.day@arkansas.gov. All comments must be received by 10:00 a.m. on August 4, 2026.

Proposed Rulemaking

Rules for Critical Access Hospitals in Arkansas

Promulgated by:
Department of Health

Title 20. Public Health and Welfare

Chapter I. Department of Health, State Board of Health, Generally

Subchapter B. Health Facilities

Part 43. Rules for Critical Access Hospitals in Arkansas

Subpart 1. Generally

20 CAR § 43-101. Purpose.

(a)(1) This part has been prepared for the purpose of establishing a criterion for minimum standards for licensure, operation, and maintenance of hospitals and related institutions in Arkansas that is consistent with current trends in patient care practices.

(2) By necessity they are of a regulatory nature but are considered to be practical minimum design and operational standards for these facilities.

(3) These standards are:

(A) Not static; and

(B) Subject to periodic revisions in the future as new knowledge and changes in patient care trends become apparent.

(b) However, it is expected that facilities:

(1) Will exceed these minimum requirements; and

(2) Shall not be dependent upon future revisions in these standards as a necessary prerequisite for improved services.

(c) Hospitals and related institutions have a strong moral responsibility for providing optimum patient care and treatment for the populations they serve.

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20 CAR § 43-102. Definitions.

For purposes of this part, the following definitions apply:

(1) "Administrator" means the person responsible for the management of any facility requiring licensure under this part;

(2)(A) "Ambulatory surgery center" means a facility in which surgical services are offered that require the use of general or intravenous anesthetics and where, in the opinion of the attending physician, hospitalization is not necessary.

(B) "Ambulatory surgery center" does not include:

(i) A medical office owned and operated by a physician or more than one (1) physician licensed by the Arkansas State Medical Board, if the medical office does not bill facility fees to a third-party payor; or

(ii) A dental office that has a Facility Permit for Moderate Sedation or a Facility Permit for General/Deep Sedation issued by the Arkansas State Board of Dental Examiners;

(3) "Alcohol/Alcohol/drug abuse inpatient treatment center" means a distinct unit within a hospital in which services are provided for the diagnosis, treatment, and rehabilitation of alcohol and drug abuse;

(4)(A) "Basic hospital services" means the services that all licensed hospitals must provide.

(B) "Basic services" consist of:

- (i) Governing body;
- (ii) Medical staff;
- (iii) General administration;
- (iv) Patient care;
- (v) Health information;
- (vi) Pharmacy;
- (vii) Food and nutrition;
- (viii) Infection prevention and control;
- (ix) Laboratory;

- (x) Radiology;
- (xi) Respiratory therapy;
- (xii) Emergency; and
- (xiii) Physical facility maintenance;

(5) "Critical access hospital" (CAH) means a hospital located in a rural area that:

(A) Is located more than a thirty-five-mile drive or, in the case of mountainous terrain or in areas with only secondary roads available, a fifteen-mile drive, from a hospital;

(B) Provides twenty-four-hour emergency care services as determined necessary for ensuring access to emergency care in each area served by a critical access hospital;

(C) Provides staffing according to the Rules for Hospitals and Related Institutions in Arkansas, 20 CAR pt. 41;

(D) Meets Centers for Medicare & Medicaid Services Conditions of Participation for Critical Access Hospitals; or

(E) Was operating as a licensed critical access hospital in Arkansas as of April 2007;

(6) "Department" means the Department of Health;

(7) "Emergency services facility" means a facility originally operated as a licensed hospital that has discontinued inpatient services but is licensed to continue to provide emergency services;

(8) "General hospital" means any facility used for the purpose of providing short-term inpatient diagnostic care and treatment, including:

(A) General medical care;

(B) Surgical care;

(C) Obstetrical care; and

(D) Specialized services or specialized treatment;

(9) "Infirmary" means any facility used for the purpose of offering temporary medical care and/or treatment exclusively for persons residing on a designated premise,

e.g., schools, reformatories, prisons, etc., and where the persons are kept for twenty-four (24) hours or more;

(10)(A) "Institution" means, for the purpose of this part, a facility that requires a license.

(B) "Institution" does not include an establishment:

(i) Operated by the federal government or by any of its agencies; or

(ii) Licensed or certified by the Division of Aging, Adult, and Behavioral Health Services of the Department of Human Services as an alcohol and drug abuse inpatient treatment center;

(11) "Licensee" means the person to whom a license is issued for the purpose of operating the institution described in the application for licensure, who shall be responsible for maintaining approved standards for:

(A) The institution of any state, county, or local government unit; and

(B) Any division, board, or agency thereof;

(12)(A) "Observation" is a designated patient status as opposed to a designated area.

(B) Patients in observation status are those patients requiring periodic monitoring and assessment necessary to:

(i) Evaluate the patient's condition; or

(ii) Determine the need for possible admissions to the hospital in an inpatient status.

(C) Usually observation status shall be for forty-eight (48) hours or less.;

(13) "Off-campus emergency department" means an emergency services department located offsite from the main hospital campus but functioning as a fully integrated department of the parent hospital;

(14)(A) "Outpatient psychiatric center" means a facility in which psychiatric services are offered for a period of eight (8) to sixteen (16) hours a day, and where, in the opinion of the attending psychiatrist, hospitalization as defined in the present licensure law is not necessary.

(B) This definition shall not include community mental health centers and clinics as they now exist;

(15) "Psychiatric hospital" means any facility or a distinct part of a facility used for the purpose of providing inpatient diagnostic care and treatment for persons having mental disorders;

(16)(A) "Recuperation center" means any facility or distinct part of a facility that includes:

(i) Inpatient beds with an organized medical staff; and

(ii) Medical services that include physician services and continuous nursing services to provide treatment for patients who are not in an acute phase of illness but who currently require primarily convalescent or restorative services, usually postacute hospital care of relatively short duration.

(B) A facility that furnishes primarily domiciliary care is not within this definition;

(17)(A) "Rehabilitation hospital or facility" means, for the purpose of this part, an inpatient care facility or a distinct part of a facility that provides rehabilitation services for two (2) or more disabled persons not related to the proprietor for more than twenty-four (24) hours through an integrated program of medical and other restorative services.

(B) A disabled person shall be considered to be an individual who has a physical or mental condition that, if not treated, will probably result in limiting the performance or activity of the person to the extent of constituting a substantial physical, mental, or vocational handicap;

(18) "Shall" means mandatory;

(19) "State Health Officer" means the Secretary for the State Board of Health; and

(20) "Surgery and general medical care hospital" means any facility limited to providing short-term inpatient surgical and general medical diagnostic care and treatment.

20 CAR § 43-103. Licensure and codes.

(a) **License required.** No general hospital or distinct part, critical access hospital or distinct part, recuperation center or distinct part, infirmary, rehabilitation facility or distinct part, outpatient surgery center, alcohol/drug abuse inpatient treatment center, psychiatric hospital or distinct part, outpatient psychiatric center, or emergency services facility may be established, conducted, or maintained in the state without first obtaining a license.

(b) **Exceptions to license requirement.** The following facilities do not require a license from the Department of Health:

- (1) A facility operated by the federal government; and
- (2) A first aid station.

(c) **Basic services required.** Every licensed hospital must provide basic services.

(d) **Application for license.**

(1) An applicant shall:

(A) File applications under oath with the Department of Health upon forms provided by the Division of Health Facilities Services; and

(B) Pay annual license fee as indicated by Acts 1997, No. 574.

(2)(A) These fees shall be:

- (i) Paid into the State Treasury; or
- (ii) Refunded to the applicant if a license is denied.

(B) The application shall be signed:

- (i) By the owner, if an individual or partnership;
- (ii) In the case of a corporation, by two (2) of its officers; or
- (iii) In the case of a governmental unit, by the head of the

governmental department having jurisdiction over it.

(C) The application shall set forth:

(i) The full name and address of the institution for which license is sought; and

(ii) Such additional information as the Department of Health may require, including affirmative evidence of ability to comply with such reasonable standards and rules as may be lawfully prescribed hereunder.

(D) The application for annual license renewal shall be postmarked no later than January 2 of the year for which the license is issued.

(E) The license applicant for an existing institution postmarked after the date shall be subject to a penalty of one dollar (\$1.00) per day for each day and every day after January 2.

(3)(A) A license issued hereunder shall:

(i) Be effective on a calendar-year basis; and

(ii) Expire on December 31 of each calendar year.

(B) A license shall:

(i) Be issued only for the premises and persons in the application;

and

(ii) Not be transferable.

(C) If the facility changes ownership, the license shall expire.

(D) The license shall be posted in a conspicuous place on the licensed premises.

(E) A license issued under previous rules shall be effective through the period for which it was issued.

(F) The adequacy of cooperative agreements between hospitals in terms of service provided by each hospital and the type of licenses issued to each hospital shall be determined by the Department of Health.

(e) Facility change of ownership.

(1) It shall be the responsibility of the licensed entity to notify the division in writing at least thirty (30) days prior to the effective date of change of ownership.

(2) The following information shall be submitted to the division for review and approval:

(A) License application;

(B) Request for Medicare certification, where applicable;

(C) Legal documents, ownership agreements, the license previously issued to the facility, and other information to support relicensure requirements; and

(D) Licensure fee as indicated by Acts 1997, No. 574.

(3)(A) For the purpose of this part the licensed entity is the party ultimately responsible for operating the facility.

(B) The same entity also bears the final responsibility:

(i) In decisions made in the capacity of a governing body; and

(ii) For the consequences of these decisions.

(f) Facility name change and/or address.

(1) The facility shall notify the division of any name and/or address change;

(2) The previously issued license shall be returned to the division; and

(3) A fee, as indicated in Acts 1997, No. 574 shall be submitted to the Division of Health Facilities Services for issuance of a new license.

(g) Management contract.

(1)(A) It shall be the responsibility of the licensed entity to notify the division in writing at least thirty (30) days prior to entering into a management contract or agreement with an organization or firm.

(B) A copy of the contract or agreement shall also be submitted to the division for review to ensure the arrangement does not materially affect the license status.

(2)(A) An organization or firm who contracts with the licensed entity to manage the healthcare facility, subject to governing body approval of operational decisions, is generally considered an agent rather than an owner.

(B) In such instances, a licensure change is not required.

(h) Separate license.

(1) An individual license shall be required for an institution maintained on separate premises even though it is operated under the same management, except in cases where the hospital management of a general hospital operates a detached building that can be utilized in a limited way for general medical care.

(2) Separate licenses are not required for separate buildings on the same grounds.

(i) **Temporary licenses.** This license shall be for:

(1) Less than one (1) year; and

(2) A time specified on the temporary license by the Department of Health.

(j) **Revocation of license.**

(1)(A) The Department of Health is empowered to deny, suspend, or revoke a license on any of the following grounds:

(i) Violation of any of the provisions of Acts 1961, No. 414 as amended by Acts 1971, No. 258, Acts 1975, No. 190, Acts 1977, No. 536, Acts 1983, No. 273, Acts 1985, No. 980, Acts 1987, No. 143, Acts 1987, No. 348, Acts 1987, No. 399, Acts 1987, No. 516, or this part; or

(ii)(a) Permitting, aiding, or abetting the commission of any unlawful act in connection with the operation of the institution.

(b) Acts 1961, No. 414, § 22, as amended.

(B) The right of appeal of any revocation shall be as specified in the appeal procedure of the Department of Health.

(2) **Note.** If services are to be temporarily suspended, a functional program, with plans and specifications as applicable, shall be submitted to the division for approval prior to such suspension.

(k) **Inspection.** Any authorized representative of the Department of Health shall have the right to enter the premises of any institution at any time in order to make whatever inspection necessary in accordance with the minimum standards and rules prescribed herein.

(l) **Centers for Medicare & Medicaid Services waivers.**

(1) When the Centers for Medicare & Medicaid Services declares a public health emergency (PHE) with the implementation of waivers that applies to Arkansas, the Department of Health may consider implementing similar waivers.

(2) If implemented, the waiver request and authorization may vary based on the type of PHE and Centers for Medicare & Medicaid Services requirements.

(m) Penalties.

(1)(A)(i) Any person, partnership, association, or corporation that establishes, conducts, manages, or operates any institution within the meaning of Acts 1961, No. 414 as amended by Acts 1971, No. 258, Acts 1975, No. 190, Acts 1977, No. 536, Acts 1983, No. 273, Acts 1985, No. 980, Acts 1987, No. 143, Acts 1987, No. 348, Acts 1987, No. 399, and Acts 1987, No. 516 without first obtaining a license therefor as herein provided, or who violates any portion of this act or rules lawfully promulgated hereunder, shall be guilty of a misdemeanor and upon conviction thereof shall be liable to a fine of:

(a) Not less than twenty-five dollars (\$25.00) nor more than one hundred dollars (\$100) for the first offense; and

(b) Not less than one hundred dollars (\$100) nor more than five hundred dollars (\$500) for each subsequent offense.

(ii) Each day such institution operates after a first conviction shall be considered a subsequent offense.

(B) Arkansas Code § 20-9-202.

(2)(A) Any institution licensed by the authority of this part that has received damage due to fire, tornado, earthquake, or manmade or natural disaster shall notify the Department of Health by telephone immediately and follow with a:

(i) Preliminary report within forty-eight (48) hours; and

(ii) Complete report when the incident has been thoroughly investigated.

(B) The submitted report shall include but not be limited to damage to the building, damage estimates, injuries to patients, staff, and the public, etc.

(C) If the Department of Health is not notified, the institution shall be assessed a fine in the amount of:

(i) Fifty dollars (\$50.00) for each day or portion thereof the incident is not reported; or

(ii) Five hundred dollars (\$500) maximum.

(n) **Codes.** See 20 CAR § 43-142, physical facilities, list of referenced publications.

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20 CAR § 43-104. Governing body.

(a)(1) An institution shall have an organized governing body that shall be legally responsible for:

- (A) Maintaining quality patient care; and
- (B) Establishing policies for the facility.

(2) The governing body shall be legally responsible for the conduct of the institution.

(b) Governing body bylaws.

(1) The governing body shall adopt written bylaws that shall be available to all members of the governing body.

(2) The bylaws shall ensure:

- (A) Maintenance of proper standards of professional work in the hospital;
- (B) The medical staff functions in conformity with reasonable standards of competency;
- (C) The method of selecting members and officers with terms and responsibilities delineated;
- (D)(i) The selection of an administrator or chief executive officer with responsibilities for operation and maintenance of the facility delineated.
 - (ii) In the absence of the administrator, an alternate with authority to act shall be designated;
- (E) Methods for establishing governing body committees with the duties of each committee delineated;
- (F) Coordination of activities and general policies of the departments and special committees;
- (G) Liaison between the governing body and medical staff with quarterly documentation;
- (H) Quarterly governing body meetings with maintenance of minutes signed by an officer;

(I) Provision for formal approval of the organization, bylaws, rules, and regulations of the medical staff and their services;

(J)(i) Admission of patients by a physician, certified nurse midwife, patient choice of physician and/or dentist, and emergency care by a physician.

(ii) All institutions governed by these standards shall arrange for one (1) or more persons duly licensed to practice medicine to be called in an emergency.

(iii) All individuals, who are not hospital employees, who make entries into the medical record, shall be credentialed through the medical staff;

(K) A method of credentialing or appointing members to the medical staff and other authorized staff;

(L) Methods by which quality assurance/performance improvement (QA/PI) is established; and

(M) Establishment of a quorum to be met in order to conduct business.

(c) **Governing body minutes.** The governing body minutes shall include at least the following information:

(1) Review, approval, and revision of the governing body bylaws and the medical staff bylaws, rules, and regulations;

(2) Election of officers as indicated in the bylaws;

(3) Documentation that the liaison between the governing body and medical staff is maintained;

(4) Appointment and reappointment of the medical staff and other authorized staff as indicated in the bylaws;

(5) Review and approval of the hospital's:

(A) Annual operating budget; and

(B) Capital expenditure plan;

(6) Review and approval of reports received from the medical staff and administration; and

(7) Review and approval of the quality assurance/performance improvement (QA/PI) plan of the facility at least annually and also documentation of the quarterly quality assurance/performance improvement (QA/PI) summaries.

20 CAR § 43-105. Medical staff.

(a)(1) All persons admitted and discharged to any institution governed by these standards shall be under the care of a person duly licensed to practice medicine in Arkansas, hereafter called physician or surgeon.

(2) In institutions where two (2) or more physicians are allowed to practice there shall be an organized medical staff.

(3) Members of the staff shall be qualified legally and professionally for the positions to which they are appointed.

(4) Individuals who are not hospital employees, who work in the hospital, shall be credentialed through the medical staff with approval from the governing body.

(5) Refer to 20 CAR § 43-135, specialized service — emergency services.

(6) **Note.** See Arkansas Code § 17-95-107 regarding requirements for healthcare organizations that credential physicians/authorized staff to use the Arkansas State Medical Board's Centralized Credentials Verification Service (CCVS).

(b) Credential files of the medical staff and other authorized staff.

(1) An individual file shall:

(A) Be maintained for each physician/other authorized staff practicing in the hospital; and

(B) Include at least the following:

(i) Verification of:

(a) Age;

(b) Year;

(c) School of graduation; and

(d) Statement of postgraduate or special training and experience;

(ii) Specific delineation of privileges requested and granted;

(iii) A detailed application signed by:

(a) The applicant;

(b) The Chair of the Credentials Committee; and

(c) An officer of the governing body;

- (iv) Documentation of the applicant's agreement to abide by the:
 - (a) Medical staff bylaws; and
 - (b) Hospital requirements;
- (v) Verification of current Arkansas license;
- (vi) Verification of each applicable physician's Drug Enforcement Administration registration;
- (vii) Verification of at least three (3) references;
- (viii) Documentation of all actions taken by the medical staff and governing board indicating:
 - (a) The type of privileges granted;
 - (b) Approval of appointment/reappointment; and
 - (c) Other related data;
- (ix) Evaluation of members' professional activities at the time of reappointment; and
- (x)(a) Nonemployee practitioners may be screened through:
 - (1) The human resources department; or
 - (2) Another hospital designee.
- (b) The requested privileges and credentialing shall be approved by the medical staff.

(2) **Note.** Hospitals shall report to the appropriate professional licensing board the names of individuals whose hospital privileges have been terminated or revoked for cause.

(c) **Medical staff bylaws.** The medical staff bylaws shall include at least the following information:

- (1) A provision stating the medical staff shall be responsible to the governing body of the facility for the:
 - (A) Quality of medical care provided for patients in the hospital; and
 - (B) Ethical and professional practices of members;
- (2) A provision stating the requirements for medical and other authorized staff membership including allied health professionals;

- (3) A provision stating the division of the medical staff and clinical departments;
- (4) A provision stating the:
 - (A) Election of officers;
 - (B) Responsibilities; and
 - (C) Terms;
- (5) A provision establishing:
 - (A) Medical staff committees;
 - (B) Functions;
 - (C) Frequency of meetings; and
 - (D) Composition (quorum);
- (6) A provision establishing frequency of general medical staff meetings, specifying attendance requirements;
- (7) A provision establishing:
 - (A) Written minutes be maintained of all medical staff meetings; and
 - (B) The minutes shall be signed by the physician chair;
- (8) A provision for an appeals process that delineates the procedures for a physician or other authorized staff to follow in challenging staff, that if ratified by the governing body adversely affects his or her appointment or reappointment to the medical staff;
- (9) A provision establishing the designation of a specific physician who shall direct each clinical/diagnostic service;
- (10)(A) A provision delineating requirements for maintaining accurate and complete medical records.
 - (B) See Health Information Services, 20 CAR § 43-113;
- (11) A provision for selection and approval of nationally recognized protocols for use in the emergency department;
- (12) A provision for approval of the bylaws and amendments by the medical staff and the governing body; and

(13) Documentation of appointments, reappointments, and approval of requested privileges to the medical and other authorized staff as specified in the bylaws, but at least every three (3) years.

(d) **Medical staff minutes.** Medical staff minutes shall include at least the following:

(1) Documentation of review of committee reports including quarterly quality assurance/performance improvement (QA/PI);

(2) Review, approval, and revision of the medical staff bylaws, rules, and regulations;

(3) Election of officers as specified by the bylaws; and

(4) Documentation of physicians designated as chairs of the committees to direct the services defined in the medical staff bylaws.

(e) **Quality assurance/performance improvement (QA/PI).**

(1)(A) The organization shall develop, implement, and maintain an ongoing program to assess and improve the quality of care and services provided.

(B)(i) A multidisciplinary committee shall meet at least quarterly to provide oversight and direction for the program.

(ii) The hospital shall maintain minutes of the meetings.

(C) A quality assurance/performance improvement plan shall be developed and maintained to describe the manner in which QA/PI activities shall be conducted in the hospital.

(D)(i) The QA/PI plan shall be reviewed and approved by the chief executive officer, medical staff, and governing body annually.

(ii) All hospital and medical staff programs, services, departments, and functions, including contracted services related to patient care, shall participate in ongoing quality assurance/performance improvement activities.

(iii) The hospital shall collect and assess data on the functional activities identified as priorities in the QA/PI plan.

(iv) Data collected shall be benchmarked against:

(a) Past performance; and/or

(b) National or local standards.

(v) Improvement strategies shall be developed for programs, services, departments, and functions identified with opportunities for improvement.

(vi) The effectiveness of improvement strategies and actions taken shall be monitored and evaluated, with documentation of conclusions regarding effectiveness.

(vii) Identify and reduce:

(a) Medical errors; and

(b) Adverse patient events.

(viii) Approved organizational abbreviation list.

(2) **Scope of QA/PI program.** The QA/PI program shall include, but not be limited to, ongoing assessment and improvement activities regarding the following:

(A) Access to care, processes of care, outcomes of care, and hospital-specific clinical data, including applicable peer review organization (PRO)/quality assurance/performance improvement organization (QA/PIO) data;

(B) Customer satisfaction (patients and families, physicians, and employees);

(C) Staff performance as it relates to the staff as a whole when reviewing aspects of care;

(D) Complaint resolution;

(E) Utilization and discharge planning data; and

(F) Organizational performance.

(3) **Program responsibilities.**

(A) The governing body shall assume overall responsibility and accountability for the organization-wide QA/PI program.

(B) The governing body, chief executive officer, and medical staff shall:

(i) Ensure QA/PI activities;

(ii) Address identified priorities; and

(iii) Be responsible for the development, implementation, monitoring, and documentation of improvement activities.

(4) **Reporting.** QA/PI activities shall be:

- (A) Reported to the governing body on at least a quarterly basis; and
- (B) Documented in the governing body meeting minutes.

(5) **Policies and procedures.** Policies and procedures pertaining to the QA/PI program that are not contained within the QA/PI plan shall be:

- (A) Maintained in a manual; and
- (B) Reviewed and approved annually.

(6) **Program evaluation.**

(A) An evaluation of the QA/PI program shall be:

- (i) Conducted by the hospital; and
- (ii) Reported to the governing body annually.

(B) The evaluation shall be:

- (i) Based upon objective data; and
- (ii) Include programs, services, departments, and functions targeted

by the hospital for improvement, as well as those conducting ongoing QA/PI activities.

(C) Changes in the QA/PI program and QA/PI plan shall be made in response to the evaluation.

(f) **Discharge planning.**

(1) There shall be a discharge plan for each patient.

(2) Discharge plans shall incorporate available community and hospital resources such as social, psychological, nutritional, and educational services to:

- (A) Meet the medically related needs of the patients; and
- (B) Facilitate the provision of follow-up care.

(3) There shall be policies and procedures developed for discharge planning that include:

- (A) Initiation of discharge planning at the time of the patient's admission;
- (B) Reassessment of patient's condition and needs prior to the patient's

discharge;

(C) Patient and family education regarding the discharge plan that includes:

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- (i) Follow-up care and treatment; and
 - (ii) Available community and hospital resources; and
- (D) Transfers and referral processes to appropriate facilities, agencies, or outpatient services as needed for follow-up or ancillary care, including necessary medical information.

(g) Organ and tissue donation.

(1) The governing body of each acute care hospital shall cause to be developed appropriate policies, procedures, and protocols for identifying and referring potential organ and tissue donors.

(2) The written policies and procedures shall include but not be limited to the following subjects:

- (A) Determination and declaration of brain death;
- (B) Organ procurement procedures:
 - (i) Identifying potential donors;
 - (ii) Referring potential donors; and
 - (iii) Obtaining consent.
- (C) Role of attending physician;
- (D) Role of the procurement coordinator (employee of procurement agencies);
- (E) Reimbursement for cost of donation;
- (F) Liabilities associated with donation;
- (G) Agreement with organ procurement agency designated by the Centers for Medicare & Medicaid Services;
- (H) A consent procedure that encourages reasonable discretion and sensitivity to the family circumstances in all decisions regarding organ and tissue donations;
- (I) Determination by the organ procurement agency personnel of the suitability of the organs and/or tissues for transplantation; ~~and~~

(J) Requirements for documentation in the patient's medical record that the family of a potential organ donor has been advised of their right to donate or decline to donate; ~~and-~~

(K) Rights of the next of kin to modify, amend, or revoke anatomical gifts per Arkansas Code §20-17-1228.

20 CAR § 43-106. General administration.

(a)(1) Each institution shall have an administrator responsible for the management of the institution.

(2) In the absence of the administrator, an alternate with authority to act shall be designated.

(3) The responsibilities of the administrator shall include:

(A) Keeping the governing body fully informed of the conduct of the hospital by:

(i) Submitting periodic written reports; or

(ii) Attending meetings of the governing body;

(B) Conducting interdepartmental meetings at regular intervals and maintaining minutes of the meetings;

(C) Preparing an annual operating budget of anticipated income and expected expenditures; and

(D) Preparing a capital expenditure plan for at least a three-year period.

(b)(1) Policies and procedures shall be provided for:

(A) The general administration of the institution; and

(B) Each department, section, or service in the facility.

(2) All policies and procedures for departments or services shall have evidence of ongoing review and/or revision.

(3) The first page of each manual shall have the:

(A) Annual review date; and

(B) Signature of the department supervisor and/or person or persons conducting the review.

(c) An accurate daily patient census sheet as of midnight shall be available to the Department of Health at all times.

(d)(1) The facility shall have visitation policies determined by the medical staff, governing body, and administration that shall include:

(A) Development by the governing body, with guidance from the medical staff and Infection Prevention and Control Committee, regarding persons under the age of twelve (12) who visit critical care areas of the hospital; and

(B) Provisions that comply with Acts 202, No. 311, known as the No Patient Left Alone Act, Arkansas Code § 20-6-401 et seq.

(2) See Appendix A.

(e) Provisions shall be made for safe storage of patients' valuables.

(f)(1)(A) Animals such as cats, dogs, birds, and fish and aquatic animals shall not be permitted in healthcare facilities.

(B)(i) A facility may ban emotional support animals.

(ii) Visitors shall be notified verbally or by posting a sign at the entrance of the facility.

(~~BC~~) Exceptions shall be made for:

(i) Service animals;

(ii) Animals that participate in pet therapy; and

(iii) Fish and aquatic animals in approved aquariums.

(~~CD~~) See 20 CAR § 43-124, pet therapy program.

(~~DE~~) All exceptions shall be approved by the Division of Health Facilities Services.

(2) Service animals shall be permitted only under the following guidelines:

(A) Only animals specifically trained as service animals shall be allowed into the facility;

(B) Service animals shall not be allowed into the facility if they are:

(i) Unhealthy;

(ii) Feverish; or

(iii) Suffering from:

(a) Gastroenteritis;

(b) Fleas; or

(c) Skin lesions;

(C)(i) Healthy, well-groomed animals shall be allowed to enter the facility into areas that are generally accessible to the public, i.e., lobbies, cafeteria, and nurses' stations on unrestricted units.

(ii) The owner of the animal shall be directed to inquire about the possibility of a visit before entering a patient's room.

(iii) Authorization to visit shall be given by a unit supervisor;

(D)(i) Service animals shall be:

(a) Walked before entering the facility; or

(b) Diapered in a manner to prevent contamination of the facility environment with excreta.

(ii) Service animals shall not be fed within the facility;

(E) Petting or playing with service animals by hospital personnel or patients shall be prohibited;

(F) Owners of service animals shall be instructed to wash their hands before having patient contact;

(G) Visiting with service animals shall be restricted in the following circumstances:

(i) The patient is in:

(a) Isolation for respiratory, enteric, or infectious diseases; or

(b) Protective isolation;

(ii) The patient, although not in protective isolation, is immunocompromised or has a roommate that is;

(iii) The patient is in an intensive care unit, burn unit, or restricted access unit of the hospital;

(iv) The patient or roommate:

(a) Is allergic to animals; or

(b) Has a severe phobia; and

(v) The patient or roommate:

(a) Is psychotic, hallucinating, or confused; or

(b) Has an altered perception of reality and is not amenable to rational explanation; and

(H) Animals that become loud, aggressive, or agitated shall be removed from the facility immediately.

(3)(A)(i) Fish and aquatic animals shall not be permitted in healthcare facilities without prior written approval by the division.

(ii)(a) Aquariums shall be approved by the:

(1) Medical staff; and

(2) Infection Prevention and Control Committee.

(b) Turtles will not be considered for approval.

(B) Aquariums shall meet the following requirements:

(i) Aquariums shall be:

(a) Self-contained;

(b) Shockproof;

(c) Breakproof; and

(d) Quiet in operation;

(ii) Aquariums shall be constructed or positioned in such a manner as to:

(a) Be leakproof;

(b) Be spillproof; and

(c) Preclude patients or staff from having direct contact with the animals or water in the aquarium;

(iii) Aquariums and associated equipment shall be cleaned frequently by appropriately trained personnel who do not have direct contact with patients or patient care items;

(iv)(a) Aquariums shall be placed only in areas that are accessed by the general public.

(b) Aquariums shall not be placed in critical care areas, i.e., nursing stations, surgery, patient rooms, ICU, etc.; and

(v) Aquariums shall be kept in a state of good repair at all times.

(C) There shall be written procedures for cleaning and caring for the aquarium.

(D) There shall be written procedures for dealing with cleanup in the event there is a major accident concerning the aquarium.

(E) Fish or aquatic animals shall be of varieties that:

(i) Do not bite or sting; and

(ii) Are considered nontoxic or nonpoisonous.

(g)(1) Each facility shall develop and maintain a risk-assessed all-hazards-written disaster plan.

(2) The plan shall:

(A) Be tailored to meet specific disaster risks present in the area such as earthquakes, tornadoes, floods, nuclear reactor failures, etc.;

(B) Include widespread disasters as well as disasters occurring within the local community and hospital facility;

(C) Provide for complete evacuation of the facility;

(D) Provide for:

(i) Care of mass casualties; and

(ii) Increased patient volume;

(E) Provide for transfer of patients, including those with hospital equipment, to an alternate site;

(F) Contain two (2) rehearsals a year, preferably as part of a coordinated drill in which other community emergency agencies participate, and:

(i) One (1) drill shall simulate a disaster of internal nature and the other external;

(ii) One (1) drill shall be planned and one (1) shall be "no notice";
and

(iii) Written reports and evaluation of all drills shall be maintained;

(G) Contain specific provisions to supply food, water, generator fuel, and other essential items for seventy-two (72) hours (applies to inpatient facilities only);

(H) Develop, maintain, and exercise redundant communication systems;
and

(I) Facilities with AWIN (Arkansas Wireless Information Network) issued equipment shall include regular maintenance and personnel training for its use.

(h)(1) There shall be a posted list of names, telephone numbers, and addresses available for emergency use.

(2) The list shall include the:

- (i) Key hospital personnel and staff;
- (ii) Local police department;
- (iii) Fire department;
- (iv) Ambulance service;
- (v) American Red Cross; and
- (vi) Other available emergency units.

(3) The list shall be reviewed and updated at least every six (6) months.

(i) There shall be rules governing the routine methods of handling and storing flammable and explosive agents, particularly in:

- (1) Operating rooms;
- (2) Delivery rooms;
- (3) Laundries; and
- (4) Areas where oxygen therapy is administered.

(j) All refrigerated areas, including freezers, shall be provided with thermometers and records maintained to document the temperatures checked on a daily or weekly basis, as required.

(k) The facility shall provide access to appropriate educational references to meet the professional and technical needs of hospital personnel.

(l)(1) A safety committee shall develop written procedures for the reporting and prevention of safety hazards.

(2) The safety committee shall meet at least quarterly or more frequently if necessary to fulfill safety objectives.

(3) Minutes of the meeting shall be maintained.

(m) All departments and/or services shall receive annual education on:

(1) Safety;

(2) Fire safety;

(3) Back safety;

(4) Infection prevention and control;

(5) Universal/standard precautions;

(6) Disaster preparedness; and

(7) Confidential information.

(n)(1) Any hospital or related institution that closes shall meet the requirements for new construction in order to be eligible for relicensure.

(2) Once a facility closes, it is no longer licensed.

(3) The license shall be immediately returned to the division.

(4) To be eligible for licensure all the latest life, safety, and health rules shall be met.

(5) Refer to 20 CAR § 43-104(d) and (j).

(o)(1) The facility administrator shall ensure the development of policies and procedures in accordance with Arkansas Code § 20-9-307 that, upon request of the patient, an itemized statement of all services shall be provided within thirty (30) days after discharge or thirty (30) days after request, whichever is later.

(2) The policy shall include a statement advising the patient in writing of his or her right to receive the itemized statement of all services.

(p) The facility shall establish a process for prompt resolution of patient grievances to include the following:

(1) The facility shall inform each patient whom to contact to file a grievance;

(2) The governing body shall approve and be responsible for the effective operation of the grievance process unless delegated in writing to another responsible individual;

(3) The facility shall establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the facility;

(4) The grievance process shall specify timeframes for:

(A) Review of the grievance; and

(B) The provisional response; and

(5) The grievance process shall include a mechanism for timely referral of patient concerns regarding quality of care to the Quality Assurance/Performance Improvement Committee.

(q) A physician or an advanced practice registered nurse, if a physician other than an emergency physician is not immediately available and the advanced practice registered nurse has been authorized by the medical staff at the hospital, shall:

(1) Pronounce the patient dead; and

(2) Document the date, time, and cause of death.

(r) Patient care providers not employed by the hospital who are involved in direct patient care shall follow hospital policies and procedures.

(s)(1) Pursuant to Arkansas Code § 20-9-302 hospitals shall not perform an abortion unless the abortion is to save the life of the pregnant woman in a medical emergency.

(2) An abortion shall only take place in a hospital or an emergency room.

(3) A physician that refers a pregnant woman for an abortion shall:

(A) Perform an obstetric ultrasound on the pregnant woman using a method that the physician and the pregnant woman agree is best under the circumstances;

(B)(i) Provide a simultaneous verbal explanation of what the ultrasound is depicting that includes the:

(a) Presence and location of the unborn child within the uterus;

and

(b) Number of unborn children depicted.

(ii) If the ultrasound image indicates that the unborn child has died, the physician or qualified technician shall inform the pregnant woman of that fact;

(C) Display the ultrasound images so that the pregnant woman may view them and document in the pregnant woman's medical record that the images were displayed to the pregnant woman;

(D) Provide a medical description of the ultrasound images, including the dimensions of the unborn child and the presence of external members and internal organs if present and viewable; and

(E) Retain the ultrasound image with the date that the ultrasound occurred in the pregnant woman's medical record.

(t) A written notice of the felony status under Arkansas Code ~~§ 5-13-202~~§ 5-13-101, et seq., of attacking a healthcare worker shall be posted in all public entrances and patient waiting area or areas of the healthcare facility utilizing the digital poster available on the Department of Health website.

(u) A healthcare provider shall not mislead any patient regarding the healthcare provider's licensure status.

(v) Hospitals must be in compliance with Acts 2023, No. 482, Arkansas Code § 20-9-314 by February 1, 2024:

(1) Hospitals are required to notify the division upon receipt of a CMS notice of noncompliance with Centers for Medicare & Medicaid Enforcement, 45 C.F.R. pt. 180;

(2) Hospitals are to notify the division upon receipt of CMS notification of return to compliance with Centers for Medicare & Medicaid Enforcement, 45 C.F.R. pt. 180; and

(3) Hospitals shall be issued fines of two hundred fifty dollars (\$250) per day for noncompliance with Centers for Medicare & Medicaid Enforcement, 45 C.F.R. pt. 180, in accordance with Arkansas Code § 20-9-314.

(w) Medical facilities or research facilities that conduct research on, with, or relating to genetic analysis or the human genome must be in compliance with Arkansas Code § 20-9-106 which requires:

(1) Medical facilities or research facilities shall not put into service any new or additional genetic sequencers or operational and research software used for genetic analysis produced by a foreign adversary, a state-owned enterprise of a foreign

adversary, a company domiciled within a foreign adversary, or a company-owned or company-controlled of a company domiciled within a foreign adversary for the purpose of conducting genetic analysis; and

(2) Medical facilities or research facilities shall report in writing all instances of subdivision (w)(1) of this section to the Secretary of Health by January 1 of each year until the equipment is no longer in use.

20 CAR § 43-107. Personnel administration.

(a) **Medical attendance.** The name, address, and telephone number of the physician or physicians attending each patient shall be recorded for ready reference.

(b) **Qualified personnel.**

(1) The hospital shall maintain a sufficient number of qualified personnel to provide:

(A) Effective patient care; and

(B) All other related services.

(2) There shall be personnel policies and procedures available.

(3) Provisions shall be made for orientation and continuing education.

(c) **Minimum age.**

(1) Personnel who care for patients shall be a minimum of sixteen (16) years of age.

(2) For any exceptions, see Subpart C of 29 C.F.R. pt. 570, Child Labor Regulations No. 3.

(d) **Employee health.**

(1) It shall be the responsibility of administration, with advice and guidance from the medical staff and/or Infection Prevention and Control Committee, to establish and enforce policies concerning preemployment physicals and employee health.

(2) The policies shall include but are not limited to:

(A) Requirements for an up-to-date health file for each employee;

(B)(i) Measures for prevention of communicable disease outbreaks, especially *Mycobacterium tuberculosis* (TB).

(ii) All plans for the prevention of transmission of TB shall conform to the most current Centers for Disease Control and Prevention Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings; and

(C)(i) Work restrictions placed on hospital personnel who are known to be:

(a) Affected with any disease in a communicable stage;

(b) A carrier of such disease; or

(c) Afflicted with:

(1) Boils;

(2) Jaundice;

(3) Infected wounds;

(4) Diarrhea; or

(5) Acute respiratory infections.

(ii) Such individuals shall not work in any area in any capacity in which there is:

(a) The likelihood of transmitting disease to patients, hospital personnel, or other individuals within the hospital; or

(b) A potential of contaminating food, food-contact surfaces, supplies, or any surface with pathogenic organisms.

(e)(1) The licensure rules promulgated by the Department of Health for hospitals and other related institutions shall be available to all personnel.

(2) All personnel shall be instructed in the requirements of the rules pertaining to their respective duties.

(f)(1) Job descriptions shall:

(A) Be developed for each employee; and

(B) Include the responsibilities or actual work to be performed.

(2) The job descriptions shall include physical, educational, and licensing or certification requirements for each job.

(g) Personnel records shall be maintained for each employee and shall include:

- (1) Current and background information covering qualifications for employment;
- (2) Records of all required health examinations;
- (3) Evidence of current registration, certification, or licensure of personnel subject to statutory regulation; and
- (4) An annual job-specific performance evaluation.

20 CAR § 43-108. Administration reports.

(a)(1) It shall be the duty of the administrator or his or her designee to report all infectious or communicable diseases in the facility to the Department of Health, as required by the Rules Pertaining to Reportable Diseases in Arkansas, 20 CAR pt. 102, (Arkansas Code §§ 20-7-109 and 110) and Centers for Medicare & Medicaid Enforcement mandatory reporting requirements for Medicare-certified facilities.

(2) See 20 CAR § 43-117(a)(3).

(b)(1) Occurrences that threaten the welfare, safety, or health of the public such as epidemic outbreaks, poisoning, etc., shall be reported either by phone or facsimile to the local or State Health Officer.

(2) The institution shall furnish other pertinent required information related to the occurrence to the department.

(c) Immediate capacity for disaster admissions shall be reported daily to the Disaster Preparedness Program of the Department of Health.

(d)(1) The facility shall electronically submit to the Division of Vital Records of the Department of Health a report on each abortion complication diagnosed or treated by the facility not later than the thirtieth day after the date on which the abortion complication was diagnosed or treated.

(2) The report must:

(A) Include the name of the physician submitting the report and type of healthcare facility submitting the report;

(B) Not identify by any means the:

(i) Physician performing the abortion; or

(ii) Patient on whom the abortion was performed; and

(C) Include:

(i) The most specific, accurate, and complete reporting for the highest level of specificity; and

(ii) The following:

(a) The date of the abortion that caused or may have caused the abortion complication;

(b) The type of abortion that caused or may have caused the abortion complication;

(c) The gestational age of the fetus at the time the abortion was performed;

(d) The name and type of healthcare facility in which the abortion was performed;

(e) The date the abortion complication was diagnosed or treated;

(f) The name and type of any healthcare facility other than the reporting healthcare facility in which the abortion complication was diagnosed or treated;

(g) A description of the abortion complication;

(h) The patient's:

(1) Year of birth;

(2) Race;

(3) Marital status;

(4) State of residence; and

(5) County of residence;

(i) The date of the first day of the patient's last menstrual period that occurred before the date of the abortion that caused or may have caused the abortion complication, if known;

(j) The number of previous live births of the patient; and

(k) The number of previous induced abortions of the patient.

(e) The facility shall report to the division transfers after midwife deliveries.

(f) A hospital shall submit reports to the department as defined in the Rules Pertaining to Hospital Discharge Data System, 20 CAR pt. 52.

20 CAR § 43-109. Patient identification.

Each patient admitted to the hospital shall have an identification bracelet applied during the admission process.

20 CAR § 43-110. Patient care service.

(a) Organization.

(1) Nursing services shall be directed by a nurse executive who is a registered nurse qualified by advanced education and management experience.

(2)(A) The nurse executive's education and experience shall be directly related to the:

- (i) Facility's stated mission; and
- (ii) Nursing care needs of the patient population.

(B) The nurse executive shall have overall authority for the development of organization-wide nursing standards, policies, and procedures that describe how patient care needs are:

- (i) Assessed;
- (ii) Evaluated; and
- (iii) Met.

(C) Development and implementation of the organization's plans for providing nursing care to the patient shall be approved by the nurse executive.

(D)(i) Policies, procedures, and standards shall be defined, documented, and accessible to the nursing staff in a written or electronic format.

(ii) Each element shall be approved by the nurse executive or designee prior to implementation.

(E) The nurse executive and nursing staff shall collaborate with appropriate governing body, medical staff, management, and other clinical leaders in developing, implementing, revising, and monitoring patient care improvement activities.

(F) The nurse executive or designee shall be responsible for orienting and maintaining adequate numbers of qualified staff for patient care.

(G)(i) Staff meetings shall be conducted at least monthly for the purpose of reviewing the quality of nursing care provided.

(ii) Meeting minutes and attendance shall be maintained.

(H) If the organization provides clinical facilities for nursing students, there shall be a written agreement that defines:

(i) The facility's responsibilities; and

(ii) Responsibilities of the educational institution, including:

(a) Supervision of students; and

(b) Responsibilities of the instructor.

(I)(i) Clinically relevant in-service educational programs shall be conducted at regularly scheduled intervals not fewer than twelve (12) times per year.

(ii) There shall be evidence of:

(a) Program dates;

(b) Attendees; and

(c) Subject matter.

(J)(i) There shall be a continuous QI program that is specific to the patient care administered.

(ii) The program shall reflect nursing staff participation including reports to appropriate hospital committees.

(b) Qualifications.

(1)(A) A current, valid license to practice nursing in Arkansas shall be held by all nurses hired in the facility as well as private duty and contract/pool nurses.

(B) There shall be a procedure to ensure all licenses are current.

(2) Licensed nursing personnel shall practice under:

(A) The Nurse Practice Act, Arkansas Code § 17-87-101 et seq.; and

(B) Current Arkansas State Board of Nursing rules.

(3)(A) The qualifications required for each category of nursing staff shall be in written policy.

(B) Job descriptions shall be available for review.

(4) There shall be documented evidence of appropriate training for all nonlicensed staff who are assigned patient care duties.

(5) The nurse executive or designee or designees participate with administration in decisions relative to the selection and promotion of nursing personnel based on qualifications and capabilities and recommend the termination of employment when necessary.

(6) All licensed nursing personnel shall be competent in life support measures.

(c) Staffing.

(1)(A) There shall be an adequate number of registered nurses on duty at all times and available for bedside care of any patient when needed on a twenty-four-hour basis.

(B) In addition, there shall be sufficient registered nurses to staff all patient care units.

(2) A registered nurse shall assign the nursing care of each patient to other nursing personnel in accordance with the:

(A) Patient's needs; and

(B) Preparation and competence of the nursing staff.

(3) There shall be written criteria to substantiate the assignments.

(d) Evaluation and review of patient care services.

(1)(A) There shall be established working relationships with other services of the hospital, both administrative and professional.

(B) The factors explaining the standard are as follows:

(i) Registered nurses confer with the physicians relative to patient care;

(ii) Interdepartmental policies affecting patient care are made jointly with the:

(a) Nurse executive; or

(b) Designee or designees; and

(iii) Procedures are established for scheduling laboratory and X-ray examinations, for ordering, securing, and maintaining supplies and equipment needed for patient care, and for ordering diets, etc.

(2)(A) There shall be ongoing review and evaluation of nursing care provided for patients.

(B) A registered nurse plans, supervises, and evaluates the nursing care for each patient in all settings where nursing care is provided.

(C)(i) Each patient shall have a plan for provision of care.

(ii) Each patient plan of care shall be current.

(iii) Plans indicate:

(a) Patient care required;

(b) How it is to be accomplished; and

(c) The methods, approaches, goals, and modifications necessary to ensure best results for the patient.

(iv) The patient's plan of care shall be initiated upon admission.

(D)(i) There shall be documentation of the nursing care provided.

(ii) The following information shall be documented:

(a) The initial patient assessment;

(b) Date and time of treatments and/or dressing changes;

(c)(1) Medication Administration Record (MAR) including the:

(A) Date, time, dosage, and manner of administration;

and

(B) Initials of the nurse administering the medication;

(2) When personnel other than nursing administer medication and the MAR is not utilized, a record of that ancillary department shall:

(A) Comply with this requirement; and

(B) Be included in the medical record;

(d) Date, time, dosage, and manner of administration of all PRN medications to include reason for administration and results;

(e) Bedtime and between-meal snacks or feedings and the percentage of diets consumed;

(f) Change in patient's appearance and/or condition;

(g) Patient complaints; and

(h)(1) Mode of discharge and to whom the patient was discharged.

(2) If a patient expires, the time the physician was called, time arrived, the time the patient was pronounced dead, and the fact that relatives were present shall be recorded.

(3) If relatives were not present, a note shall be made regarding:

(A) Their notification; and

(B) Disposition of the patient's belongings.

(E)(i) A registered nurse shall observe each patient at least once per shift and the observations shall be documented in the patient's medical record.

(ii) **Note.** Block charting and cosignatures are not acceptable.

(e) Patient care facilities and equipment.

(1) There shall be no more beds maintained in the building than the number of beds for which the hospital is licensed except in the case of a public disaster or national emergency, and then only as a temporary measure.

(2) No beds shall be in the hallway or on the floor except in case of emergency.

(3) Children under the age of sixteen (16) years shall not be cared for in a room with an unrelated adult patient.

(4) Provisions shall be made for safe storage of patients' valuables.

(5) All facilities for cleaning and storage of patient care supplies and equipment shall be used only for the purpose for which they are designed.

(6) Thermometers shall not come in contact with more than one (1) patient without disinfection or proper covers.

(7) All single-use equipment used by a patient shall either be:

- (A) Sent home with the patient at the time of discharge; or
- (B) Destroyed.

(8)(A) Only currently dated equipment and supplies shall be available for patient care.

- (B) All equipment shall be kept clean and in good condition.

(9)(A) Observation is a designated patient status as opposed to a designated area.

(B) Patients in observation status are those patients requiring periodic monitoring and assessment necessary to:

- (i) Evaluate the patient's condition; or
- (ii) Determine the need for possible admission to the hospital in an

inpatient status.

(C) Usually observation status shall be for forty-eight (48) hours or less.

(D) Patients in observation status may be accommodated within the facility:

- (i)(a) In private, semiprivate, or multipatient rooms.

(b) Furniture shall be arranged to:

- (1) Provide adequate room for patient care procedures; and
- (2) Prevent the transmission of infection;

(ii)(a) Cubicle curtains, privacy screens, or an approved equivalent shall be provided for patient privacy in all multipatient rooms.

(b) The utilization of such curtains or screens shall be such that each patient shall have complete privacy;

- (iii) Each room or cubicle shall be provided with:

- (a) Oxygen;
- (b) Vacuum; and
- (c) A nurse call button;

(iv) Hand hygiene facilities shall be available within the area;

(v)(a) Hospital-grade furniture shall be provided.

(b) Bed rails shall be provided on beds;

(vi)(a) For each area in which a patient bed is utilized, a reading light shall be provided for each bed.

(b) The location and design shall be such that the light is not annoying to other patients;

(vii) Patient toilets shall be provided and accessible to all patients;
and

(viii) Adequate space shall be provided for medical supplies.

(E) Patients that remain in observation status for a period of twenty-four (24) hours or more shall have provided to them accommodations equivalent to the accommodations they would have if they were admitted as an inpatient.

20 CAR § 43-111. Medications.

(a)(1) All medical orders (medications and treatments) shall be:

(A) Documented; and

(B) Signed by the prescriber.

(2) Telephone/verbal orders should be used infrequently.

(3) When used they shall be:

(A) Given only to licensed nurses; and

(B) Signed by the prescriber.

(b)(1) No medication shall be dispensed or administered without a written order signed by a licensed prescriber.

(2) A pharmacist may:

(A) Receive telephone or verbal orders for medications from a prescriber;
and

(B) Record them on the medical record.

(c)(1) Medications shall be administered by licensed nursing personnel in accordance with the current Nurse Practice Act, Arkansas Code § 17-87-101 et seq.

(2) Other personnel may administer medications only in accordance with their current Practice Act (e.g., respiratory, physical therapy).

(d)(1) Blood transfusions and intravenous medications administered by licensed nursing personnel shall be in accordance with state law.

(2) If not administered by a registered nurse, only licensed nursing personnel who have documentation of training shall be permitted to administer blood transfusions and intravenous medications.

(e) There shall be an effective hospital procedure for reporting:

(1) Transfusion reactions; and

(2) Adverse medication reactions.

(f)(1) All medications shall be properly labeled and stored in a specifically designated:

(A) Medication cabinet;

(B) Cart; or

(C) Room.

(2) At nursing stations, medications shall only be accessible to licensed nursing personnel and pharmacists.

(3) In specialty units and treatment areas, medications shall only be accessible to licensed nursing personnel, pharmacists, and designated licensed personnel consistent with that unit (e.g., respiratory, physical therapy).

(g)(1) Refrigeration shall be provided for the proper storage of biologicals and other medications.

(2) Medications shall be stored in a separate compartment or area from food.

(3) Employee foods and/or medications shall be stored in a separate refrigeration area.

(4) An internal thermometer shall be provided and checked daily, or at least weekly when the unit is closed, with documentation to ensure temperatures between thirty-six and forty-six degrees Fahrenheit (36°F – 46°F) or two to eight degrees Celsius (2°C – 8°C).

(5) Refrigerated controlled substances shall meet the requirement for double-lock security.

(h)(1) Unused or damaged medications shall be returned to the pharmacy.

(2) All medications with incorrect or soiled labels shall be returned to the pharmacy for relabeling.

(i)(1) In addition to patients' medical records, a record of the procurement and disposition of each controlled substance shall be maintained at each nursing and specialty unit.

(2) Each entry on the disposition record shall reflect the:

- (A) Actual dosage administered to the patient;
- (B) Patient's name;
- (C) Date;
- (D) Time; and
- (E) Signature of the licensed person administering the medication.

(3) Licensed personnel who may legally administer controlled substances shall include only those personnel authorized by their current Practice Act.

(4) Any error of entry on the disposition record shall follow a policy for:

- (A) Correction of errors; and
- (B) Accurate accountability.

(5) If the licensed person who procures the medication from the double-lock security is not the licensed person who administers the medication, there shall be record of the activity conducted by each licensed person.

(j)(1) When breakage or wastage of a controlled substance occurs, the amount given and the amount wasted shall be:

- (A) Recorded by the licensed person who wasted the medication; and
- (B) Verified by the signature of a licensed person who witnessed the wastage.

(2) Documentation shall include or policy shall delineate how the medication was wasted.

(3) In addition to the above referenced licensed personnel (see subsection (i) of this section), licensed pharmacists shall be allowed to witness wastage of controlled substances.

(k)(1) There shall be an audit each shift change of all controlled substances stocked on the unit.

(2) At nursing stations such counts shall be:

(A) Recorded by the oncoming nurse; and

(B) Witnessed by the offgoing nurse.

(3) At other units, audits shall be performed by two (2) licensed personnel.

(4) In each case, both licensed personnel shall sign the record with notation made as to date and time of the audit.

(5) If discrepancies are noted, the director of nursing, the department director, as applicable, and the director of pharmacy shall be notified.

(6) As with the witnessing of wastage, licensed pharmacists shall be allowed to witness controlled substance audits.

(7) For facilities utilizing medication dispensing systems to dispense controlled substances, the facility shall have a process and evidence available to ensure audit of controlled substances was conducted at shift change.

(l) If specialty units are not staffed on every shift, controlled substances shall be audited by two (2) licensed personnel on each shift that is covered by licensed personnel.

(m) Controlled substances in areas that are covered only by on-call personnel shall be audited each shift the area is used and at least weekly, whichever time frame is less.

(n) Solutions and medications for "external use only" shall be kept separate from other medications.

(o)(1) When a patient is discharged, the unused portion of the patient's medication may be sent home with the patient:

(A) On direct written order of the attending physician; and

(B) Only after the medication has been relabeled by the pharmacy.

(2) Documentation shall include the amount dispensed to the patient and quantities shall be consistent with the immediate needs of the patient.

(p) Policies and procedures shall be developed and implemented for the handling of medications brought into the facility by the patient.

(q)(1) All medication errors and adverse drug reactions shall be reported to the attending physician.

(2) A copy of all medication errors and adverse drug reactions shall be sent to the director of nursing or designee, QA/PI Committee, and when appropriate to the director of pharmacy.

(r)(1) Records generated by automatic medication distribution devices shall comply with this part.

(2) Policies and procedures for the usage of automatic medication distribution devices shall be approved administratively by the Division of Health Facilities Services prior to their usage.

(s) **Drug security.**

(1)(A) The pharmacist, with support from the Pharmacy and Therapeutics (P&T) Committee, is ultimately responsible for drug security throughout the facility.

(B) Applicable licensed personnel at nursing and specialty units shall maintain the daily security of medications at their respective units.

(2) Access to medications shall be limited to designated licensed personnel at all times.

(3) Medications dispensed to nursing and specialty units shall be kept locked in accordance with all federal and state regulations.

(4) Emergency-type medications ("crash cart", "crash kit") as approved by the P&T Committee shall be secured with a breakaway seal under the following conditions:

(A) The quantities of medication are limited;

(B) A list of medications stocked with quantities listed is posted on the emergency cart or container;

(C) The breakage of the seal clearly indicates that entry has occurred and said broken seal cannot be repaired without obvious evidence;

(D) Any remaining medications shall be secured and accessible only to licensed personnel:

(i) Whenever the seal has been broken; and

(ii) Before a new seal is installed;

(E)(i) Applicable personnel shall check the cart for the integrity of the seal each shift.

(ii) Documentation shall reflect that the seal is intact.

(iii) The emergency cart shall be stored in an area observable by licensed personnel;

(F)(i) The quantities of a controlled substance stocked in a cart or container shall be limited to a maximum of two (2) single doses of Schedule III, IV, or V drugs.

(ii) No Schedule II drugs shall be included in this stock; and

(G) Pharmacy services shall check the condition of the carts or containers as part of the monthly inspections of nursing and specialty units.

(5) Controlled substances maintained as floor stock at nursing and specialty units shall be stored separately from other medication, under double-lock security.

(6) For patient safety, Schedule III, IV, and V controlled substances in unit dose packages and dispensed in quantities limited to a maximum of a two-day supply may be stored with that patient's other medication.

(7) All medications shall be locked in the absence of immediate visual supervision by licensed personnel.

(8) When a hospital operates an outpatient pharmacy that stocks medications in various clinical areas, stock lists, records, and security measures shall be in compliance with the requirements for nursing and specialty units.

(9)(A) Distribution of sample legend medications shall not be permitted by hospitals.

(B) Samples are defined as any prescription-only medication that is:

(i) Not intended to be sold; and

(ii) Intended to promote the sale of the medication.

(10)(A) Medication security as provided by automatic medication distribution devices shall comply with this part.

(B) Policies and procedures for security provisions shall be approved administratively by the Division of Health Facilities Services prior to usage of automatic medication distribution devices.

20 CAR § 43-112. Restraints.

(a) Restraint use should be:

- (1) Implemented in the least restrictive manner possible;
- (2) Applied in accordance with safe and appropriate techniques; and
- (3) Ended at the earliest possible time.

(b)(1) Each order for the application of restraints shall:

- (A) Be time-limited; and
- (B) Include the type of restraint to be used.

(2) Restraint orders shall not be written:

- (A) As a standing order; or
- (B) On an as-needed basis (PRN).

(c)(1) Restraints, either physical or chemical, shall be applied only after less-restrictive measures have failed.

(2) Restraints shall not be used as a:

- (A) Matter of convenience for the staff; or
- (B) Tool for disciplining the patient.

(3) When the use of a restraint is clinically indicated, it shall be used only in accordance with the order of a physician or nonphysician licensed medical professional who has been appropriately credentialed by the medical staff with approval by the governing body.

(d) Documentation of a comprehensive assessment and modification to the plan of care shall include:

- (1) The less-restrictive measures attempted;
- (2) Justification for the continued need of restraint; and
- (3) That the patient and/or significant other has been informed of the reason for restraint use.

(e) Documentation in the patient's record regarding any type of restraint shall include the times the restraint was applied, released, and discontinued as well as evidence of continual assessment, monitoring, and reevaluation of the patient's condition during the restraint incident.

(f) When restraint use is ordered by other than the attending physician, the attending physician shall be informed as soon as possible.

(g) Patients in leather or locked restraints shall be under constant observation.

(h) All staff that have direct patient contact shall have ongoing education and training in the proper and safe use of restraints.

20 CAR § 43-113. Health Information Services.

(a) General requirements.

(1) A medical record shall be maintained for each patient admitted for care in the hospital.

(2) The original, or a copy of the original when the original is not available, of all reports shall be filed in the medical record.

(3) The record shall be:

(A) Permanent; and

(B) Either:

(i) Typewritten; ~~or~~

(ii) Legibly written in blue or black ink; or

(iii) Maintained electronically.

(4) All ~~typewritten~~ reports shall include the:

(A) Date of dictation; and

(B) Date of transcription.

(5) All dictated records shall be transcribed within forty-eight (48) hours.

(6) Errors shall be corrected ~~by either~~:

(A) By:

(i) Drawing a single line through the incorrect data;

(Bii) Labeling it as "Error"; and

____ (Eiii) Initialing and dating the entry; or

(B) Per electronic medical record formatting.

(7) Additional patient records room requirements are provided in 20 CAR § 43-160, physical facilities — health information unit.

(8)(A) Disease, operation, and physicians' indices shall be maintained (manual, abstract, or computer).

(B) Records shall be indexed within one (1) month following discharge.

(C) Indices maintained on computer shall be retrievable at any time for research or quality assurance/performance improvement monitoring.

(9)(A) Records of discharged patients shall be coded in accordance to accepted coding practices.

(B) Records shall be coded within one (1) month of the patient's dictated discharge summary.

(10)(A) Relevant educational programs shall be conducted at regularly scheduled intervals with no fewer than twelve (12) per year.

(B) There shall be written documentation with:

(i) Employee signatures;

(ii) Program title/subject;

(iii) Presenter;

(iv) Date; and

(v) Outlines or narrative of presented program.

(11)(A) A master patient index shall be maintained by the Health Information Services.

(B) Index information shall include at least the full name, address, birth date, and the medical record number of the patient.

(C) The index:

(i) May be maintained manually or on computer; and

(ii) Shall contain the dates of all patient visits to the facility.

(D) If the index is maintained on computer, there shall be a policy and procedure on permanent maintenance.

(12) Birth certificates shall be completed according to the current Rules for the Administration of Vital Records, 20 CAR pt. 1, Department of Health.

(13)(A) A unit record system shall be maintained.

(B) A unit record is defined as all inpatient and outpatient visits for each patient being filed together in one (1) unit.

(14)(A) A policy and procedure manual for the Health Information Management Department shall be developed.

(B) The manual shall have evidence of ongoing review and/or revision.

(C) The first page of each manual shall have the:

(i) Annual review date; and

(ii) Signature of the Health Information Management Department supervisor and/or person or persons conducting the review.

(15)(A) A qualified individual shall be employed to direct the hospital's Health Information Management Department.

(B) If a Registered Health Information Administrator (RHIA) or a Registered Health Information Technician (RHIT) is not employed as director on a full-time basis by the hospital, a consultant shall make periodic visits to:

(i) Evaluate functions of the Health Information Management Department; and

(ii) Train personnel.

(16) All patient records, whether stored within the Health Information Management Department or other areas, either within the facility or away from the facility, shall be protected from destruction by fire, water, vermin, dust, etc.

(17)(A) Medical records shall be considered confidential.

(B) Only authorized personnel shall have access to the medical records.

(C) All medical records, including those filed outside the Health Information Management Department, shall be secured at all times.

(D) If authorized personnel are not available, the Health Information Management Department shall be locked.

(E) Records shall be available to authorized personnel from the Department of Health.

(18) Release of medical information shall be restricted by the facility's policies and procedures.

(19)(A) All medical records shall be retained in either the original, microfilm, or other acceptable methods for ten (10) years after the last discharge.

(B) After ten (10) years a medical record may be destroyed provided the facility permanently maintains the information contained in the master patient index.

(C) Complete medical records of minors shall be retained for a period of two (2) years after the age of majority.

(20)(A) Procedures shall be developed for the retention and accessibility of the patients' medical records if the hospital or other facility closes.

(B) The medical records shall be:

(i) Stored for the required retention period; and

(ii) Accessible for patient use.

(C) The provider must notify the Department of Health of the entity responsible for maintaining the medical records following the facility's closure.

(21)(A) All entries into the medical record shall be legible.

(B) There shall be no erasures or obliterations of the original information contained in a medical record.

(22) Medical records shall be complete and contain all required signed documentation, including physician reports, no later than thirty (30) days following the patient's discharge date.

(23)(A) Patient records shall be destroyed by burning or shredding.

(B) Patient records shall not be disposed of in:

(i) Landfills; or

(ii) Other refuse collection sites.

(24) A QA/PI program shall be:

(A) Continuous; and

(B) Specific to the services.

(25)(A) In the event of a physician's death or permanent incapacitation, incomplete medical records shall be reviewed in a manner approved by the medical staff.

(B) Approval to file incomplete medical records shall be obtained in a manner approved by the medical staff and a statement explaining the circumstances be placed in each record.

(b) Authentication of medical record entries.

(1)(A) Each entry into the medical record shall be authenticated by the individual who is the source of the information.

(B) Entries shall include:

- (i) All documents, observations, notes; and
- (ii) Any other information included in the record.

(2)(A) Signatures shall be at least the:

- (i) First initial;
- (ii) Last name; and
- (iii) Title.

(B) Computerized signatures may be either by:

- (i) Code;
- (ii) Number;
- (iii) Initials; or
- (iv) The method developed by the facility.

(3)(A) The hospital's medical staff and governing body shall adopt a policy regarding dictation that permits authentication by electronic or computer-generated signature.

(B) The policy shall identify those categories of the staff within the hospital that are authorized to authenticate patient records using electronic or computer-generated signatures.

(4)(A) At a minimum, the policy shall include adequate safeguards to ensure confidentiality.

(B) Each user shall be assigned a unique identifier that is generated through a confidential code.

(C) The policy shall include penalties for inappropriate use of the identifier.

(D) The user shall certify in writing that he or she is the only person authorized to use the signature code.

(E)(i) The hospital shall periodically monitor the use of identifiers.

(ii) The process by which the monitoring shall be conducted shall be described in the policy.

(5) The system shall make an opportunity available to the user to verify that the:

(A) Document is accurate; and

(B) Signature has been properly recorded.

(6) Each report generated by a user shall be separately authenticated.

(7) A user may terminate authorization for use of electronic or computer-generated signature upon written notice to the director of Health Information Services.

(8)(A) Rubber stamp signatures shall be acceptable if a letter from the physician is on file explaining that the:

(i) Physician shall be the only person using the stamp; and

(ii) Stamp shall remain in his or her possession at all times.

(B) The signature stamp shall be the full legal name of the physician with his or her professional title.

(9)(A) Transcribed reports dictated by other than the attending physician shall be signed by the:

(i) Credentialed individual dictating the report; and

(ii) Attending physician.

(B) Dictation of reports by other than the attending physician is limited to:

(i) History;

(ii) Physical;

(iii) Discharge summary;

- (iv) Operative reports; and
- (v) Progress notes.

(C) Reports dictated by resident physicians for training purposes require only the signature of the attending physician.

(c) Electronic health information.

(1) Policies and procedures governing electronic health information within the organization and with external entities shall be adopted by the governing body.

(2)(A) The policies and procedures shall provide for the use, exchange, security, and privacy of electronic health information.

(B) The policies and procedures shall provide for standardized and authorized availability of electronic health information for:

- (i) Patient care;
- (ii) Administrative purposes; and
- (iii) Research.

(C) The policies and procedures will be in compliance with current guidelines and standards as established in federal and state status.

(d) Record content.

(1) Identification data shall include at least the following:

- (A)(i) Patient's full name.
- (ii) Maiden name if applicable;
- (B) Patient's:
 - (i) Address;
 - (ii) Telephone number; and
 - (iii) Occupation;
- (C) Date of birth;
- (D) Age;
- (E) Sex;
- (F) Marital status (M.S.D.W.);
- (G) Dates and times of admission and discharge;
- (H) Full name of physician;

(I) Name and address of nearest relative or person or agency responsible for patient, and occupation of responsible party;

(J) Name, address, and telephone number of person or persons to notify in case of emergency; and

(K) Medical record number.

(2)(A) A general consent for medical treatment and care.

(B) This shall be signed by the patient or guardian.

(C) Written or verbal consent shall not release the hospital or its personnel from upholding the rights of its patients, including but not limited to the right to:

(i) Privacy;

(ii) Dignity;

(iii) Security;

(iv) Confidentiality; and

(v) Freedom from abuse or neglect.

(3)(A) A consent for:

(i) A do-not-resuscitate order; or

(ii) Otherwise withholding or withdrawing treatment of a minor.

(B) The consent shall:

(i) Include the written or verbal consent of at least one (1) parent or guardian of the minor;

(ii) Include the signature of two (2) witnesses attesting the consent was given by at least one (1) parent or guardian when the consent was given verbally; and

(iii) Be documented in the minor's medical record, specifying the:

(a) Parent or guardian who gave consent;

(b) Witnesses present; and

(c) Date and time the consent was obtained.

(C) The consent does not apply if the minor is:

(i) Married, pregnant, or emancipated;

(ii) Incarcerated in the Division of Correction or the Division of Community Correction; or

(iii) In the custody of the Department of Human Services.

(D) Does not apply if a reasonable diligent effort of at least seventy-two (72) hours without success has been made to contact and inform each known parent or guardian of intent to:

(i) Issue a do-not-resuscitate order; or

(ii) Otherwise withhold or withdraw treatment so as to allow the natural death of a minor.

(E) The parent or guardian may revoke the consent verbally or in writing.

(4) Clinical reports shall include the following and shall comply with listed requirements:

(A)(i) A history and physical examination (HPE) shall be in the patient's medical record within forty-eight (48) hours of the patient's admission to the facility.

(ii) The HPE must be authenticated by the attending or treating physician and shall contain the following:

(a)(1) Family (medical) history and review of systems.

(2) If noncontributory, the record shall reflect such;

(b) Past medical history;

(c)(1) Chief complaint or complaints.

(2) A brief statement of the nature and duration of the symptoms that caused the patient to seek medical attention as stated in the patient's own words;

(d) Present illness with dates or approximate dates of onset;

(e) Physical examination; and

(f) Provisional or admitting diagnosis or diagnoses;

(iii) History and physical examinations may be completed up to thirty (30) days prior to admission if the examination is updated at the time of admission.

(iv) The updated HPE must be authenticated by the attending or treating physician;

(B)(i) Progress notes shall be recorded, dated, and signed.

(ii) The frequency of the physician's progress notes shall be determined by the patient's condition.

(iii) Dictated progress notes:

(a) Are acceptable; and

(b) Shall be placed in the patient's medical record within forty-eight (48) hours;

(C) Orders including verbal orders shall be authenticated with a legible and dated signature in a timely manner as defined by medical staff bylaws;

(D)(i) A discharge summary shall recapitulate:

(a) The significant findings and events of the patient's hospitalization; and

(b) His or her condition on discharge;

(ii) The discharge summary must be authenticated by the attending or treating physician within thirty (30) days of the patient's discharge.

(iii) The final diagnosis shall be stated in the discharge summary;

(E)(i) Autopsy findings shall be documented in complete protocol within sixty (60) days and the provisional anatomical diagnosis shall be recorded within seventy-two (72) hours.

(ii) A signed authorization for autopsy shall be obtained from the next of kin and documented in the medical record before an autopsy is performed;

(F)(i) Original, signed diagnostic reports (laboratory, X-rays, CAT scans, EKGs, fetal monitoring, EEGs) shall be filed in the patient's medical record.

(ii) Physicians' orders shall accompany all treatment procedures.

(iii) Fetal monitor and EEG tracings may be filed separately from the medical record if accessible when needed;

(G) Reports of ancillary services (dietary, physical therapy, respiratory care, social services, etc.) shall be included in the patient's medical record; and

(H) Reports of medical consultation if ordered by the attending physician shall be included in the patient's medical record within time frames established by the medical staff.

(e) **Records of complementary departments.** In addition to the general record content requirements stated above, subsections (f) – (g) of this section are required, as applicable.

(f) **Surgery records.**

(1)(A) A specific consent for surgery shall be documented prior to the surgery/procedure to be performed, except in cases of emergency, and shall include the:

- (i) Date;
- (ii) Time; and
- (iii) Signatures of the patient and witness.

(B) Consent shall be:

- (i) Obtained by the surgeon; and
- (ii) Documented in the patient's medical record.

(C) Abbreviations are not acceptable.

(2)(A) A history and physical examination (HPE) on admission containing medical history and physical findings shall be documented in the patient's medical record prior to surgery.

(B)(i) In cases of emergency surgery, an abbreviated physical examination and a brief description of why the surgery is necessary shall be included in the HPE.

(ii) See subsection (d) of this section.

(C) The HPE must be authenticated by the attending or treating physician or surgeon.

(3)(A) An anesthesia report, including preoperative evaluation and postoperative assessment, shall be documented by the anesthesiologist and/or certified registered nurse anesthetist (CRNA).

(B)(i) The preevaluation and post-assessment shall be dated and timed.

(ii) Preoperative anesthesia evaluation shall be completed prior to the patient's surgery.

(iii) **Report of anesthesia.** A CRNA who has not been granted authority by a facility, as a Drug Enforcement Administration registrant, to order the administration of controlled substances shall give all orders as verbal orders from the:

(a) Supervising physician;

(b) Dentist; or

(c) Other person lawfully entitled to order an anesthetic.

(iv)(a) Postanesthesia assessment shall be documented in the medical record prior to the patient's discharge, not to exceed forty-eight (48) hours after the patient's surgery.

(b) If the patient is in need of continued observation, the anesthetist shall be readily available.

(c) Discharge criteria shall be established and approved by the medical staff and governing body.

(d) If the patient meets the discharge criteria within a three-hour period postoperatively, a postanesthesia assessment is not required.

(4)(A) An individualized operative report shall be:

(i) Written or dictated by the physician or surgeon immediately following surgery; and

(ii) Signed within seventy-two (72) hours.

(B) The report shall describe in detail:

(i) Techniques;

(ii) Findings;

(iii) Preoperative and postoperative diagnosis; and

(iv) Tissues removed.

(5)(A) A signed pathological report shall be maintained in the medical record of all tissue surgically removed.

(B) A specific list of tissues exempt from pathological examination shall be developed by the medical staff.

(g) Obstetrical records.

(1) A pertinent prenatal record shall be updated upon admission, or history and physical examination signed by the physician shall be:

(A) Available upon the patient's admission; and

(B) Maintained in the patient's medical record.

(2) A record of labor and delivery authenticated by the physician shall be maintained for every obstetrical patient.

(3) Documentation of the patient's recovery from delivery shall be maintained.

(4) Nurses' postpartum record, graphics, and nurses' notes shall be maintained.

(h) Newborn records.

(1)(A) A newborn history and physical examination shall be completed by the physician within twenty-four (24) hours of birth.

(B) The following additional data shall be required:

(i) History of the newborn delivery (sex, date of birth, type of delivery, and anesthesia given the mother during labor and delivery); and

(ii) Physical examination (weight, date, time of birth, and condition of infant after birth).

(2) There shall be a consent for circumcision if applicable.

(3) A procedure note for circumcision shall be documented by the physician.

(4)(A) A discharge note or summary describing the condition of the newborn at discharge and follow-up instructions given to the mother must be prepared and included in the medical record.

(B) The discharge note or summary must be authenticated by the attending or treating physician.

(5)(A) Hospitals shall comply with state law and Department of Health requirements for newborn testing.

(B) See:

(i) Rules Pertaining to Testing of Newborn Infants, 20 CAR pt. 107;

and

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(ii) Arkansas Code § 20-15-301 et seq.

(6) Birth certificates shall be completed on all infants born in the hospital, or admitted as a result of birth, in accordance with the requirements of the Division of Vital Records of the Department of Health.

20 CAR § 43-114. Medical record requirements for outpatient services, emergency room, and observation services.

(a) **Outpatient records.** An outpatient record shall:

(1) Be completed for each outpatient; and

(2) Include the following:

(A)(i) History and physical examination of the patient.

(ii) Not applicable if for diagnostic services and/or outpatient therapy services;

(B) Orders and reports of:

(i) Diagnostic services; and

(ii) Outpatient therapy services;

(C) Patient's diagnosis and summary of treatment received, recorded by the attending physician;

(D) Documentation of any medications administered;

(E) Progress notes for subsequent clinic visits recorded by applicable disciplines (practitioners);

(F)(i) Outpatient surgery record requirements.

(ii) See also 20 CAR § 43-113(f), Health Information Services; and

(G) Discharge instructions.

(b) **Emergency room records.**

(1) An emergency room record shall:

(A) Be completed for each patient who presents for treatment at the emergency room; and

(B) Include the following:

(i) Patient identification;

- (ii) Date and the following times:
 - (a) Admission;
 - (b) Time physician was notified of patient's presence in the emergency room;
 - (c) Time of physician's arrival if applicable; and
 - (d) Discharge;
- (iii) History (when the injury or onset of symptoms occurred);
- (iv) Vital signs;
- (v) Nurses' assessment and physical findings;
- (vi) Diagnosis;
- (vii)(a) Record of treatment including documentation of verbal orders and of medication quantities administered with the initials of the person or persons administering the medications.
 - (b) Also, type and amount of local anesthetic, if administered;
- (viii) Diagnostic reports with specific orders noted;
- (ix) Instructions to patients for follow-up care (e.g., do not drive after receiving sedatives, return to physician's office for removal of sutures in one (1) week);
- (x) Disposition of case;
- (xi) Signature of patient or his or her representative;
- (xii) Signed and dated discharge order; and
- (xiii) The ambulance record shall be transferred with the patient.

(2) **Note.** Emergency room records shall be completed within twenty-four (24) hours of the patient's visit.

(c) **Observation records.**

(1)(A) A record of every patient admitted to an observation status shall be maintained.

(B) The observation record shall include, at a minimum:

- (i) Patient identification data;
- (ii) Physician's diagnosis and therapeutic orders dated and timed;
- (iii) History and physical;

- (iv) Physician's progress notes, including results of treatment;
- (v) Nursing assessment by a registered nurse;
- (vi) Nursing observations;
- (vii) Results of all diagnostic testing;
- (viii) Medication Administration Record;
- (ix) Allergies;
- (x) Patient education;
- (xi) Plan for follow-up treatment; and
- (xii) Referrals.

(2) **Note.** Observation records shall be completed on patients who stay less than twenty-four (24) hours.

(d) **Psychiatric records.** The basic medical record requirements for psychiatric patients shall be the same as for other patient records with the following additions:

(1) The identification data shall include the patient's legal status on the face sheet;

(2) A proper consent or authority for admission shall be included;

(3) A psychiatric evaluation shall be completed by the attending physician within sixty (60) hours of admission that includes the following:

(A) The patient's chief complaints and/or reaction to hospitalization, recorded in patient's own words if possible;

(B) History of present illness including:

(i) Onset; and

(ii) Reason for current admission;

(C) Past history of any psychiatric problems and treatment, including a record of patient's activities (social, education, vocational, interpersonal and family relationships);

(D) Past psychiatric history of patient's family;

(E) Mental status that includes at least:

(i) Attitude and general behavior;

(ii) Affect;

- (iii) Stream of mental activity;
- (iv) Presence or absence of delusions and hallucinations;
- (v) Estimate of intellectual functions;
- (vi) Judgment; and
- (vii) An assessment of orientation and memory;

(F) Strengths such as knowledge, interests, skills, aptitudes, experience, education, and employment status written in descriptive terms to be used in developing the master treatment plan; and

(G) Diagnostic impressions and recommendations;

(4) A history and physical examination shall:

(A) Be documented by a physician; and

(B) Include a neurological examination within twenty-four (24) hours of admission;

(5)(A) Social service records, including report of interviews with patient, family members, and others shall be included for each admission.

(B) Social assessment and plan of care shall be completed within forty-eight (48) hours of admission;

(6) Reports of consultation, psychological evaluations, reports of electroencephalograms, dental records, and reports of special studies shall be included in the records when applicable;

(7)(A) An interdisciplinary master treatment plan shall be developed for each patient and included in the medical record within sixty (60) hours of admission.

(B) The treatment plan shall:

(i) Involve all staff who have contact with the patient; and

(ii) Include at a minimum:

(a) Problems and needs relevant to admission and discharge as identified in the various assessments, expressed in behavioral and descriptive terms;

(b) Strengths (assets) including skills and interests;

(c) Problems both physical and mental that require therapeutic management;

(d)(1) Long-term and short-term goals describing the desired action or behavior to be achieved.

(2) Goals shall be:

(A) Relevant;

(B) Observable; and

(C) Measurable;

(e) Treatment modalities individualized in relation to patient's needs;

(f) Evidence of patient's involvement in formulation of the plan;

(g) Realistic discharge and aftercare plans;

(h)(1) Nursing assessment and progress notes integrated into the master treatment plan.

(2) Reviews and revisions of the nursing plan of care shall be as required under 20 CAR § 43-110, patient care service;

(i) Signatures of all staff involved;

(j) Date master treatment plan was implemented; and

(k) Staff responsibilities;

(8) The treatment received by the patient shall be documented in such a manner and with such frequency as to ensure that all active therapeutic efforts such as individual and group psychotherapy, medication therapy, milieu therapy, occupational therapy, industrial or work therapy, nursing care, and other therapeutic interventions are included;

(9)(A) Progress notes shall be recorded by the physician, social worker, and others involved in active treatment modalities at least as often as the patient is seen.

(B) The notes shall contain recommendations for revisions in the treatment plan;

(10) Nursing notes shall be written as required under 20 CAR § 43-110, patient care service;

(11) The discharge summary shall include a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up of aftercare as well as a brief summary of the patient's condition on discharge; and

(12) The psychiatric diagnosis contained in the final diagnosis and included in the discharge summary shall be written in the terminology of the current American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.

20 CAR § 43-115. Pharmacy.

(a)(1) All hospitals shall have adequate provision for pharmaceutical services regarding the procurement, storage, distribution, and control of all medications.

(2) There shall be compliance with all federal and state regulations, including Arkansas State Board of Pharmacy Rules, 17 CAR pt. 160.

(b) **Definitions.** As used in this section:

(1) "Hospital employee" means any individual employed by the hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital;

(2)(A) "Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are prepared for distribution and administration for the use and/or benefit of patients in a hospital licensed by the Department of Health.

(B) The "hospital pharmacy" shall also mean the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are compounded for dispensing to:

- (i) Hospital employees;
- (ii) Members of the immediate families of hospital employees;
- (iii) Patients being discharged; and
- (iv) Other persons in emergency situations;

(C) "Hospital pharmacy" shall also mean the provision of pharmaceutical services as defined in the Pharmacy Practice Act by a pharmacist to a patient of the hospital;

(3) "Licensed pharmacist" means any person licensed to practice pharmacy by the Arkansas State Board of Pharmacy who provides pharmaceutical services as defined in the Pharmacy Practice Act to patients of the hospital;

(4) "Modified unit dose distribution system" means a system that meets the requirement of a "unit dose distribution system" provided that up to a seventy-two-hour supply may be sent to the floor once a week if the system has been reviewed and approved administratively by the Arkansas State Board of Pharmacy;

(5) "Qualified hospital personnel" means persons other than licensed pharmacists who perform duties in conjunction with the overall hospital pharmaceutical services for inpatients; and

(6) "Unit dose distribution system" is a pharmacy-coordinated method of dispensing and controlling medications in hospitals in which medications are dispensed in single-unit packages for a specific patient on orders of a physician where not more than a twenty-four-hour supply of said medication is dispensed, delivered, or available to the patient.

(c)(1) Hospitals maintaining and using mechanical storage and delivery machines for legend drugs shall have such machines stocked only by pharmacy services.

(2) Drugs may be obtained from such machines only by licensed personnel in accordance with their Practice Act acting under the prescribed rules of safety procedures as promulgated by the individual hospital using said machine.

(3) Limited amounts of Schedule II – V controlled substances may be stocked in the machines provided the following requirements are met:

(A) Pharmacy services possesses the only key necessary to stock the machine; and

(B) Policies and procedures specify the licensed personnel having access and responsibility for the medications.

(4)(A) The person removing a medication for administration shall record at least the patient's name and the name, strength, and amount of medication on a record that is maintained by the pharmacy department.

(B) The record shall also be signed by the person removing the medication.

(C) The removal of controlled substances shall comply with the recordkeeping requirements of 20 CAR § 43-111, medications.

(D) Pharmacy services shall audit stock levels as needed to replace medications.

(5) Use of the machines shall not be to circumvent adequate pharmaceutical services.

(d) **Compounding, dispensing, and distributing.**

(1) **Compounding.** The act of selecting, mixing, combining, measuring, counting, or otherwise preparing a drug or medication.

(2) **Dispensing.**

(A) A function restricted to licensed pharmacists that involves the issuance of:

(i) One (1) or more doses of a medication in containers other than the original, with such new containers being properly labeled by the dispenser as to content and/or directions for use as directed by the prescriber;

(ii) Medication in its original container with a pharmacy-prepared label that carries to the patient the directions of the prescriber as well as other vital information; and/or

(iii) A package carrying a label prepared for nursing station use.

(B) The contents of the container may be for one (1) patient (individual prescription) or for several patients, such as a nursing station medication container.

(3) **Distributing.**

(A) Distributing, in the context of this part, refers to the movement of a medication from a central point to a nursing station medication center.

(B) The medication shall be in the originally labeled manufacturer's container or in a prepackaged container labeled according to federal and state laws and regulations:

(i) By a pharmacist; or

(ii) Under his or her direct and immediate supervision.

(e) **Pharmacy and Therapeutics Committee.** There is a committee of the medical staff to confer with the pharmacist in the formulation of policies, explained as follows:

(1)(A) A Pharmacy and Therapeutics (P&T) Committee composed of at least one (1) physician, the administrator or representative, the director of nursing service or representative, and the pharmacist is established in the hospital.

(B) It represents the organizational line of communication and the liaison between the medical staff and the pharmacist;

(2) The committee assists in the formulation of broad, professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures in conformance with Food and Drug Administration and manufacturers' recommendations on the safe administration of drugs and all other matters relating to drugs in hospitals;

(3) The committee performs the following specific functions:

(A) Serves as an advisory group to the hospital medical staff and pharmacist on matters pertaining to the choice of drugs;

(B) Develops and approves the drug formulary and all drug lists annually and makes interim revisions as needed;

(C) Establishes standards concerning the:

(i) Use and control of investigational drugs; and

(ii) Research in the use of recognized drugs;

(D) Evaluates clinical data concerning new drugs or preparations requested for use in the hospital;

(E) Makes recommendations concerning:

(i) Drugs to be stocked on the nursing unit floors; and

(ii) Emergency drug stocks; and

(F) Reviews and approves drug-related policies and procedures;

(4)(A) The committee develops and approves policies and procedures for all nursing personnel assigned the responsibility of preparing and administering intravenous (IV) admixtures.

(B) The pharmacist shall be involved in the review of the drug order, calculations, and preparation whenever possible.

(C) The committee should consider the appropriate category of personnel (registered nurse or LPN) and degree of training necessary to make judgments and calculations involved in IV admixture programs;

(5) The committee ensures that medications dispensed to outpatients, emergency room patients, and discharged patients comply with all federal and state laws and regulations; and

(6) The committee:

(A) Meets at least quarterly; and

(B) Reports to the medical staff by written report.

(f) Pharmacy operations.

(1) The hospital has a pharmacy directed by a licensed pharmacist.

(2) The pharmacy is administered in accordance with accepted professional principles.

(3) **Pharmacy supervision.** There is a pharmacy directed by a licensed pharmacist, defined as follows:

(A) The director of pharmacy is responsible to the administration of the hospital and Arkansas State Board of Pharmacy for developing, supervising, and coordinating all the activities of:

(i) The pharmacy department; and

(ii) All pharmacists providing professional services in the hospital; and

(B)(i) All licensed pharmacists who provide pharmaceutical services as defined by the Pharmacy Practice Act shall practice under policies, procedures, and protocols approved by the director of pharmacy.

(ii) These policies, procedures, and protocols shall be subject to review and approval by the Arkansas State Board of Pharmacy.

(g) **Physical facilities.** Facilities are provided for the storage, safeguarding, preparation, and dispensing of drugs, defined as follows:

(1) Drugs are issued to floor units in accordance with approved policies and procedures;

(2)(A) Drug cabinets on all units shall be checked monthly by qualified pharmacy personnel.

(B) All floor stocks are properly controlled;

(3)(A) A careful determination of the functions of a department will regulate the space to be allocated, the equipment necessary to carry out the functions, and the number of personnel required to utilize the equipment and to render a given volume of service, as these functions relate to the frequency or intensity of each function or activity.

(B) Adequate equipment shall specifically relate to services rendered and functions performed by the hospital pharmacy.

(C) Equipment lists will relate to the following services and functions:

(i) Medication preparation;

(ii) Library reference facilities;

(iii) Record and office procedures;

(iv) Sterile product manufacturing;

(v) Bulk compounding (manufacturing);

(vi) Product control (assay, sterility testing, etc.); and

(vii) Product development and special formulations for medical staff.

(D)(i) Pharmacy shall maintain equipment and supplies necessary to:

(a) The hospital pharmacy's safe, efficient, and economical operation; and

(b) Meet the patient's needs.

(ii) Pharmacy shall maintain updated drug reference resources approved by the hospital for staff use, online, hard-copy, or both; and

(4) Special locked storage space is provided to meet legal requirements for storage of:

- (A) Controlled drugs;
- (B) Alcohol; and
- (C) Other prescribed drugs.

(h) **Personnel.** Personnel competent in their respective duties are provided in keeping with the size and activity of the department, explained as follows:

(1) The director of pharmacy is assisted by an adequate number of additional licensed pharmacists and other such personnel as the activities of the pharmacy may require to ensure quality pharmaceutical services; and

(2) The pharmacy, depending upon the size and scope of its operations, is staffed by the following categories of personnel:

- (A) Chief pharmacist (director of pharmacy);
- (B) One (1) or more assistant chief pharmacists (assistant director of pharmacy);
- (C) Staff pharmacists;
- (D) Pharmacy residents where program has been activated;
- (E) Trained nonprofessional pharmacy helpers (qualified hospital personnel); and
- (F) Clerical help.

(i) **Emergency pharmaceutical services.** Through the administrator of the hospital, the P&T Committee shall establish policies and procedures that include but are not limited to the following:

(1) Upon admission to the emergency room on an outpatient basis and when examined by the physician where medications are prescribed to be administered, a record shall be kept on file in the emergency room admission book or a copy of the emergency room medication order must be kept by the pharmacist to be readily accessible, for control and other purposes, as required by this part;

(2)(A) If the physician wishes the patient to have medication to be taken with them from the emergency room supplies, the amounts to be taken shall be sufficient to last until medication may be obtained from local pharmacies, in any case not to exceed a forty-eight-hour supply.

(B) All state and federal laws shall be observed concerning all records, labeling, and outpatient dispensing requirements;

(3) Take-home prescriptions for anti-infectives issued to patients at the time of discharge from the emergency room, dispensed by a pharmacist, shall be quantities consistent with the medical needs of the patient; and

(4) Hospitals that have obtained a Continuity of Care endorsement through the Arkansas State Board of Pharmacy may sell drugs and medication at retail for emergency room patients or patients upon discharge from the hospital for off-premises, personal use in an outpatient setting for either up to a thirty-one-day supply or a single commercially available package size as a continuation or supplement to hospital or emergency department treatment within the elements of the said agreement.

(j) Pharmacy records and labeling.

(1) Records are kept of the transactions of the pharmacy and correlated with other hospital records where indicated.

(2) All medication shall be properly labeled.

(3) Such record and labeling requirements are as follows:

(A) The pharmacy establishes and maintains, in cooperation with the accounting department, a satisfactory system of records and bookkeeping in accordance with the policies of the hospital for:

(i) Maintaining adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies; and

(ii) Charging patients for drugs and pharmaceutical supplies;

(B) A record of procurement and disbursement of all controlled drugs is maintained in such a manner that the disposition of any particular item may be readily traced;

(C) The pharmacist shall receive and provide service pursuant to the perusal of the physician's original order or a direct copy thereof, except in emergency situations wherein the pharmacist may provide service pursuant to a verbal order or to an oral or written transcription of the physician's order, provided that the pharmacist shall receive and review the original or direct copy;

(D) A record shall be maintained for each patient (inpatient or outpatient) containing the name of the patient, the prescribing physician, the name and strength of the drugs prescribed, the name, the quantity, and the pharmacist's initials for all medications dispensed;

(E)(i) The label of each medication container prepared for administration to inpatients shall bear the:

(a) Name and strength of the medication;

(b) Expiration date; and

(c) Lot or control number.

(ii) The label on the medication or the container into which the labeled medication is placed shall bear the:

(a) Name of the patient; and

(b) Room number; and

(F) The label of each outpatient's individual prescription medication container bears the:

(i) Name of the patient, prescribing physician, directions for use, and the name and strength of the medication dispensed unless directed otherwise by the physician; and

(ii) Date of dispensing.

(k) Control of toxic or dangerous drugs.

(1) Policies are established to control the administration of toxic or dangerous drugs with specific reference to the duration of the order and the dosage, explained as follows:

(A) The medical staff has established a written policy that all toxic or dangerous medications not specifically prescribed as to the time or number of doses will be automatically stopped after a reasonable time limit set by the staff;

(B) The classifications ordinarily thought of as toxic or dangerous drugs are:

(i) Controlled substances;

(ii) Anticoagulants;

- (iii) Antibiotics;
- (iv) Oxytocics; and
- (v) Cortisone products; and

(C) All deteriorated nonsterile, nonlabeled, or damaged medication shall be destroyed by the pharmacist, with the exception of controlled substances.

(2) All controlled drugs (Schedule II, III, IV, and V) shall be listed and a copy sent along with drugs to the Department of Health, by registered mail or delivered in person, for disposition.

(m) **Policy and procedure manual.**

(1) A policy and procedure manual pertaining to the operations of the hospital pharmacy, with updated revisions adopted by the P&T Committee of each hospital, shall be prepared and maintained at the hospital.

(2) The policy and procedure manual shall include at a minimum the following:

(A) Provisions for procurement, storage, distribution, and drug control for all aspects of pharmaceutical services in the hospital;

(B) Specialized areas such as surgery, delivery, ICU and CCU units, and emergency room stock and usage of medication shall be specifically outlined;

(C) Detailed job descriptions and duties of each employee by job title working in the pharmacy department shall be:

- (i) Developed; and
- (ii) Made a part of these policies and procedures; and

(D) The pharmacy policy and procedure manual shall be subject to review and approval by the Arkansas State Board of Pharmacy on request from the Arkansas State Board of Pharmacy.

(n) **Employee prescription medication.**

(1)(A) There will be a prescription on file for all prescription drugs dispensed to:

- (i) Hospital employees; and
- (ii) Their immediate families.

(B) These records will be kept separate from all inpatient records.

(2) The only person or persons entitled to have employee prescriptions filled will be the:

- (A) Employee listed on the hospital payroll; and
- (B) Members of their immediate family.

(o) **Patient discharge medication.** Any take-home prescription dispensed to patients at time of discharge from the hospital shall be for drugs and quantities consistent with the immediate needs of the patient.

(p) **Licensed pharmacist personnel requirements.**

(1) The minimum requirements for licensed pharmacists in hospitals are:

(A)(i) A general hospital, surgery and general medical care, maternal and general medical care hospital, chronic disease hospital, psychiatric hospital, and rehabilitative facility licensed for greater than fifty (50) beds, as determined by the institution license issued by the Department of Health, shall require the services of one (1) pharmacist on the basis of forty (40) hours per week with such additional pharmacists as are necessary in the opinion of the Arkansas State Board of Pharmacy to perform required pharmacy duties as are necessary in keeping with the size and scope of the services of the hospital pharmacy's safe and efficient operation.

(ii) Hospitals providing specialized or unique patient care services may request approval from the Arkansas State Board of Pharmacy to be exempt from the requirement of a pharmacist on duty forty (40) hours per week.

(iii) The request for exemption shall provide adequate written documentation to justify the services of a pharmacist such hours as are necessary to perform required pharmacy services, followed by an appearance before the Arkansas State Board of Pharmacy for final approval of the request;

(B)(i) The above classified hospitals, licensed for fifty (50) beds or fewer, as determined by the institution license issued by the Department of Health shall require the services of a pharmacist such hours as in the opinion of the Arkansas State Board of Pharmacy and the State Board of Health are necessary to perform required pharmacy duties in keeping with the size and scope of the services of the hospital pharmacy safe and efficient operation.

(ii) The pharmacist shall be onsite at least five (5) days per week to perform and review pharmacy dispensing, drug utilization, and drug distribution activities.

(iii) A pharmacist shall be available to provide emergency services to the staff when the pharmacy is closed; and

(C) Recuperation centers, outpatient surgery centers, and infirmaries.

(i) If the infirmery, recuperation center, or outpatient surgery center has a pharmacy department, a licensed pharmacist shall be employed to administer the pharmacy in accordance with all state and federal laws regarding drugs and drug control.

(ii) If the infirmery, recuperation center, or outpatient surgery center does not have a pharmacy department, it has provisions for promptly and conveniently obtaining prescribed drugs and biologicals from a community or institutional pharmacy.

(iii)(a) If the infirmery, recuperation center, or outpatient surgery center does not have a pharmacy department but does maintain a supply of drugs, a licensed pharmacist shall:

(1) Be responsible for the control of all bulk drugs; and

(2) Maintain records of their receipt and disposition.

(b) The pharmacist shall dispense drugs from the drug supply, properly labeled, and make them available to appropriate nursing personnel.

(iv) All medication for patients shall be on an individual prescription basis.

(2) A pharmacist-in-charge, who is employed at any facility permitted by the Arkansas State Board of Pharmacy where a forty-hour work week is required, may also be the pharmacist-in-charge at a hospital licensed for fifty (50) beds or fewer by the Department of Health.

(q) Responsibility of a pharmacist in hospital pharmacy.

(1) The pharmacist is responsible for the:

(A) Control of all medications distributed in the hospital where he or she practices; and

(B) Proper provision of all pharmaceutical services.

(2) The following aspects of medication distribution and pharmaceutical service are functions involving professional evaluations or judgments and may not be performed by supportive personnel:

(A)(i) Interpretation and certification of the medication ordered.

(ii) This involves a number of professional responsibilities such as the determination of:

(a) Accuracy and appropriateness of dose and dosage schedule;

(b) Such items as:

(1) Possible drug interactions;

(2) Medication sensitivities of the patient; and

(3) Chemical and therapeutic incompatibilities; and

(c) Accuracy of entry of medication order to patient's medication profile; and

(B) Final certification of the prepared medication.

(r) Pharmacy technicians.

(1) "Pharmacy technician" means those individuals identified by the Arkansas State Board of Pharmacy, exclusive of pharmacy interns, who:

(A) Are regular paid employees of the hospital; and

(B) Assist the pharmacist in pharmaceutical services.

(2)(A) "Supervision" means that the responsible pharmacist shall be physically present to observe, direct, and supervise the pharmacy technician at all times when the pharmacy technician performs acts specified in this part.

(B) The supervising pharmacist is totally and absolutely responsible for the actions of the pharmacy technician.

(3) The pharmacist and pharmacy technician or technicians shall comply with all applicable sections of the Arkansas State Board of Pharmacy Rules, 17 CAR pt. 160,

with regards to tasks, responsibilities, duties, ratios, and supervision in the hospital setting.

(4)(A) There shall be documentation by each technician of all duties and tasks performed in the preparation and processing of medication.

(B) The pharmacist shall be responsible for the final check and verification of all technician duties and tasks.

(C) The performance, check, and verification shall be recorded on a record maintained by the department that shall include the signature, initial or initials, or other identifying mark of each person.

(s) Operation of pharmacy department when pharmacist is not present.

(1)(A) A limited supply of backup medications may be utilized for patient needs only at times when the pharmacist is not present.

(B) This stock shall be accessible only to approved licensed personnel.

(C) A record shall be maintained that identifies the:

(i) Medication obtained; and

(ii) Personnel obtaining it.

(D) The pharmacist shall then review this record when he or she returns to the facility to ensure compliance with the physician's orders.

(E) Medications shall be replaced to stock as needed.

(2) At no time will the hospital pharmacy be open and in operation unless a licensed pharmacist is physically present except:

(A)(i) Entrance may be obtained for emergency medication as set forth in the pharmacy policy and procedure manual when the pharmacy is closed outside its normal operation hours.

(ii) The medical staff shall approve a method by which individual nursing personnel may be authorized by name and qualification to remove:

(a) Only one (1) dose if the drug is not of the unit dose packaging type; or

(b) If the medication is unit-dosed, enough medication to last until the pharmacist returns can be removed.

(iii) A record listing all medications obtained should be maintained and the pharmacist shall check for compliance with the physician's orders when he or she returns to the facility.

(iv) Controlled substances shall not be accessible unless daily counts are performed and documented; and

(B) When the pharmacist is summoned away from the pharmacy and there are other qualified personnel left in the pharmacy, the personnel left in the pharmacy shall perform only those functions authorized within this part.

(3) A pharmacist shall be available to provide medication consultation.

(t) **Medication utilization.** The pharmacist, with the advice and guidance of the P&T Committee, shall participate in:

(1)(A) Discussions of reports of medication errors, with:

- (i) Trends noted;
- (ii) Conclusions made; and
- (iii) Recommendations suggested.

(B) If there are no errors to report, this shall be stated;

(2)(A) Discussions of adverse drug reactions with:

- (i) Trends noted;
- (ii) Conclusions made; and
- (iii) Recommendations suggested.

(B) Proper reports of appropriate reactions shall be reported to the:

- (i) Full medical staff; and/or
- (ii) Food and Drug Administration reporting system.

(C) If there are no adverse reactions to report, this shall be stated;

(3) Reviews of results of monitoring conducted according to approved criteria for antibiotics prescribed for prophylactic and therapeutic reasons;

(4) Reviews of other drug utilization in the facility, as appropriate; and

(5)(A) Formulation of an official record of each meeting maintained as minutes.

(B) The written report shall be forwarded to the P&T Committee, QA/PI Committee, and/or the medical staff for review and consideration with at least a quarterly frequency.

(u) **Electronic data processing in hospital pharmacies.** All hospitals utilizing electronic data processing systems shall comply with the Arkansas State Board of Pharmacy Rules, 17 CAR pt. 160.

(v) **Maintenance and retention of drug records.** All drug records, including but not limited to purchase invoices, official dispensing records, prescription and inventory records shall be:

(1) Kept in such a manner that all data is readily retrievable; and

(2) Retained as a matter of record by the pharmacist for at least two (2) years.

(v) **Retail pharmacy.** A nonprofit, tax exempt, or governmentally funded hospital may operate a retail pharmacy per Arkansas Code § 17-92-401, et seq.

(w) **Abandoned controlled substances.**

(1) Policies and procedures shall be developed and implemented for the handling of medications brought into the facility.

(2) Controlled substances that meet the definition of abandoned drug, in accordance with Arkansas Code § 20-56-202, may be disposed of in accordance with the respective facilities' policy and procedure.

(3) Abandoned controlled substances shall be disposed of in compliance with federal, state, and local laws, rules, or regulations.

(4) The following procedure shall be a part of the disposal process:

(i) The disposal of the controlled substance or substances occurs in the presence of two state licensed healthcare professionals including but not limited to pharmacists, nurses and physicians; and

(ii) The disposal of the controlled substance or substances shall be documented in a designated log or provider form to include product description, product quality, date of destruction, and signatures of both licensed healthcare professionals involved in the disposal.

(5) Records of abandoned controlled substance disposal shall be filed apart from other controlled substance records and kept for a minimum of two (2) years.

20 CAR § 43-116. Food and nutrition services.

(a) Administration.

(1)(A) The food and nutrition services shall be under the daily, including weekends, onsite supervision of a qualified individual.

(B) The individual shall be at a minimum a certified dietary manager and:

(i) Be responsible for the daily management of clinical and administrative dietetic aspects of the service by formulating, reviewing, and revising policies and procedures for all food and nutrition services practices;

(ii) Ensure that all personnel in the service are oriented in their respective duties;

(iii) Implement a maintenance program to ensure food service facilities, equipment, and utensils are:

(a) Maintained in a safe, clean, sanitary manner; and

(b) Replaced at specific intervals or as needed;

(iv) Participate on hospital-wide departmental committees as required;

(v)(a) Ensure that trained staff are maintained for daily administrative and clinical nutrition practices.

(b) A minimum of a two-week current work schedule shall be posted and reflect all positions including the department director; and

(vi) Develop, implement, and maintain a system for recordkeeping relating to all department functions dependent on the department's scope of services, e.g., patient assessments, counseling, diet instructions, temperatures, educational programs, etc.

(C)(i) A hospital within a hospital may contract with the host hospital for food and nutrition services.

(ii) Contracted services shall:

- (a) Be under a current agreement; and
- (b) Meet all requirements of this section.

(2)(A) Policies and procedures shall have evidence of ongoing review and/or revision.

(B) The first page of each manual shall have the:

- (i) Annual review date; and
- (ii) Signature of the department supervisor and/or person or persons

conducting the review.

(3) Policies and procedures shall include:

- (A) Job descriptions and performance evaluations;
- (B) Orientation;
- (C) Preventive maintenance;
- (D) Infection prevention and control measures;
- (E) Safety practices; and
- (F) Cleaning of equipment and applicable areas.

(4)(A) Clinically relevant educational programs shall be conducted at regularly scheduled intervals with not fewer than twelve (12) per year.

(B) There shall be evidence of:

- (i) Program dates;
- (ii) Attendance; and
- (iii) Subject matter.

(5)(A) Nutrition services shall have an ongoing QA/PI program that addresses both clinical and administrative issues.

(B) A mechanism for reporting results of audits shall be provided, to include:

- (i) Indicators monitored;
- (ii) Thresholds/standards established;
- (iii) Results;
- (iv) Corrective plan/corrective action taken; and
- (v) Follow-up.

(6) Time and duty schedules for all hourly employees shall be maintained.

(7)(A) Diet manual shall be authorized by the medical staff, reviewed and revised as needed to reflect current recognized dietary practices.

(B) A cover page shall be affixed with the date of review and appropriate signatures, and a copy of the manual shall be located on each patient unit.

(C) Use of electronic diet manuals is acceptable.

(8) Menus shall:

(A) Be planned/approved by the registered dietitian and meet the nutrition needs of the patients in accordance with the current recommended dietary guidelines of the Food and Nutrition Board of the National Research Council and the currently approved facility diet manual in accordance with the written diet order;

(B)(i) Be dated at least one (1) week in advance.

(ii) The current week's menus shall be posted and available in the kitchen.

(iii) The meals prepared and served shall correspond with:

(a) The posted menu; or

(b) Written diet orders;

(C) Not be restrictive in nature (e.g., seasoning, fat, sodium, sugar content) unless required by a modified/therapeutic diet order; and

(D)(i) Be of equivalent nutrition value when substitutions/changes are made.

(ii) Menus/production schedules showing all changes shall be retained for at least thirty (30) days.

(9)(A) Diets shall be in writing and signed by a physician or a midlevel practitioner if privileged by the medical staff and governing body.

(B) Dietitians may issue orders for patient diets if authorized by the medical staff.

(C) Notification according to facility policy shall:

(i) Be made to the nutrition services department on a timely basis;

(ii) Be kept current; and

(iii) Include the:

(a) Current date; and

(b) Patient's name, room number, and diet order.

(b) Food services.

(1)(A) At least three (3) meal equivalents shall be served daily at regular intervals approximately five (5) hours apart.

(B) No more than fifteen (15) hours shall elapse between the serving of the evening meal and the morning meal.

(C) The meals shall be served at approximately the same hour each day.

(2) Food shall be prepared in:

(A) Accordance with approved menus and standardized recipes; and

(B) A manner to conserve nutritive value, flavor, and appearance.

(3) Food shall:

(A) Meet patient needs; and

(B) Be attractive, palatable, and served at proper temperatures.

(4) An identification system shall be implemented for patient trays to ensure that each patient receives the appropriate diet as ordered.

(5) Nourishing bedtime snacks appropriate to the patient's needs shall be made available.

(6) Only foods prepared and stored under the direction of nutrition services in accordance with the Rules Pertaining to Retail Food Establishments, 20 CAR pts. 190 – 197, shall be served to patients.

(7)(A) All individuals who assist patients in the preparation, heating, reheating, or consumption of food or sanitation of foodware and kitchen equipment, etc., while in the facility or on the facility grounds shall be:

(i) Under the direction of nutrition services; and

(ii) In compliance with the Rules Pertaining to Retail Food

Establishments.

(B) Documentation of educational programs on food preparation, safety, and sanitation shall be performed for all applicable personnel (e.g., occupational therapy, nursing) by nutrition services at least annually.

(8) Food shall not be consumed in the kitchen.

(9)(A) Food shall be transported in a manner that:

(i) Maintains safe food temperatures; and

(ii) Prevents contamination.

(B) Food carts shall not block:

(i) Corridors/exits;

(ii) Emergency equipment; or

(iii) Patient doorways.

(10) All storage containers/foodstuffs shall be stored a minimum of six inches (6") above the floor on nonporous, easily cleaned racks, dollies, or shelving in a manner that:

(A) Protects the food or food-contact surfaces from splash and other contamination; and

(B) Permits easy cleaning of the storage area.

(11) Plastic milk crates shall not be permitted for storing of food or equipment except for the intended use for milk storage.

(12) Temperature documentation of all food refrigerators/freezers in the kitchen and cafeteria shall be performed a minimum of three (3) times per day at opening, midoperation, and closing of the department.

(13) Temperature documentation of all nourishment refrigerators/freezers in patient care areas shall be performed at least daily.

(14)(A) Proper temperatures of vending machines containing potentially hazardous foods shall be ensured daily by the facility.

(B) Vending machines shall be equipped with a thermometer easily visible to food service personnel for the purposes of monitoring the temperature of the internal environment.

(C) These machines shall have the capacity to render themselves inoperable if temperatures in excess of forty degrees Fahrenheit (40°F) are maintained for more than two (2) hours.

(D) Documentation of such downtime shall be maintained to include remedial action taken.

(15) If, for any reason, the refrigeration equipment does not maintain the appropriate temperature:

(A) Action shall be taken; and

(B) A record of remedial action and downtime shall be recorded and maintained by the facility.

(16)(A) Temperature documentation of the dish machine shall be recorded with each meal and these records shall be maintained by the facility.

(B) If the temperatures and, if applicable, dwell times, are not maintained properly action shall be taken and a record of remedial action, back-up procedures used, and downtime shall be maintained by the facility.

(17) If the facility uses a chemical method for sanitizing food preparation ware and serving ware, a record of the water temperature, the chemical used, and appropriate parts per million (ppm) shall be maintained by the facility at each use.

(18)(A) The temperature of the hot and cold potentially hazardous foods shall be recorded at least at the beginning and end of meal service that continues for more than fifteen (15) minutes.

(B) If meal service lasts for fifteen (15) minutes or less, food temperature documentation is required only at the beginning of food service.

(19) Documentation of the testing/calibration of food/refrigeration/freezer thermometers shall be performed according to manufacturers' recommendations.

(20) Food thermometers shall be:

(A) Sanitized after each use; and

(B) Stored in a manner that prevents contamination.

(21) Only dietary and authorized personnel shall be allowed in the kitchen.

(22) Sanitation shall be in accordance with the Rules Pertaining to Retail Food Establishments.

(c) **Food safety/sanitation.**

(1) Whole eggs and raw meat shall be stored:

(A) Separately; and

(B) In a way that prevents contamination of other food items in refrigerated units.

(2)(A) Reheated food shall attain a temperature above one hundred sixty-five degrees Fahrenheit (165°F) prior to placement in:

(i) Steam tables;

(ii) Warmers; or

(iii) Other hot food storage units.

(B) Steam tables, warmers, or other food storage units shall not be used for the rapid heating of potentially hazardous food.

(3)(A) Disposable gloves shall be worn to eliminate direct handling of food.

(B) Gloves shall be properly discarded after being used, torn, or contaminated.

(4) Ground beef or ground beef products shall be cooked to an internal temperature of one hundred sixty degrees Fahrenheit (160°F) or higher.

(5) Potentially hazardous food shall be tempered or thawed only:

(A) In designated tempering units at a temperature not to exceed forty-five degrees Fahrenheit (45°F);

(B) In general refrigeration units at a temperature not to exceed forty degrees Fahrenheit (40°F);

(C) As part of the conventional cooking process; or

(D) In a microwave provided the food is immediately transferred to conventional cooking process.

(6) Potentially hazardous food that is left over shall be labeled as such with the date and time it was removed from service.

(7) Potentially hazardous food shall be:

(A) Chilled to a temperature below forty degrees Fahrenheit (40°F); and

(B) Retained for no longer than forty-eight (48) hours.

(8)(A) Food-contact surfaces, i.e., cutting boards, of all equipment and utensils shall be sanitized by:

(i) Immersion for at least one-half (1/2) minute in clean, hot water at a temperature of at least one hundred eighty degrees Fahrenheit (180°F); or

(ii) Any other method approved by the Division of Health Facilities Services.

(B) Countertops and other huge industrial equipment shall be washed down with concentrated solutions.

(9) Clean linens, mopheads, and cloths shall be stored in a manner to prevent contamination prior to use.

(10)(A) Soiled linens, etc., shall be stored covered, separately from clean linen, food storage, preparation, and serving areas.

(B) Containers for holding such items shall be made of nonabsorbent materials.

(C) Soiled linens shall be removed from the department daily.

(11)(A) Food inventory shall be handled on a first-in, first-out basis.

(B) A system for labeling and dating canned, dry, and potentially hazardous foods shall be implemented.

(12) Potentially hazardous frozen foods removed from freezer storage to be thawed shall be labeled with the date of pull from the freezer for thawing.

(13) Supplies and perishable foods for a twenty-four-hour period and nonperishable foods for a three-day period shall be on the premises to meet the requirements of the planned menus.

(14) **Note.** This part is referenced to the Rules Pertaining to Retail Food Establishments.

(d) **Clinical services.**

(1) **Clinical dietitian/nutritionist.**

(A) Shall be a registered dietitian or registry-eligible and evaluate and oversee the delivery of effective nutrition care based on current, recognized nutrition practices.

(B) If not full-time, make regularly scheduled visits to accomplish the following:

(i) Review, revise, and approve a current diet manual for facility use;

(ii) Review, revise, approve, and implement:

(a) Nutrition care policy and procedures, standards of nutrition care, and nutrition care protocols; and

(b) The nutrition services QA/PI program;

(iii) Coordinate nutrition care through communication with other patient care services;

(iv) Provide for the:

(a) Initiation of nutrition screening of all patients upon admission; and

(b) Periodic screening of patients during their hospital stay;

(v) Provide for the nutrition assessment of patients at nutrition risk as defined by the medical staff and collaborate with the physician on the findings of the evaluation;

(vi) Ensure competency of all nutrition services personnel who:

(a) Perform assessments;

(b) Perform counseling;

(c) Develop care plans; and

(d) Participate in discharge planning;

(vii) Provide to the facility evidence of continuing education hours;

(viii) Perform orientation, preceptorship, and ongoing training/educational programs for staff;

(ix) Review and revise nutrition counseling/diet education practices that are individualized to patient needs;

(x) Monitor the enforcement of all policies, procedures, and practices relating to food safety and sanitation;

(xi) Develop, implement, and maintain a system for recording data related to patient care;

(xii) Collaborate with nursing and pharmacy to provide food/drug interaction counseling; and

(xiii) If the dietitian is a consultant, submit reports to the facility administrator reflecting services performed at each regularly scheduled visit.

(2) Nutrition screening and documentation.

(A) Nutrition screening shall be completed within twenty-four (24) hours of admission on all patients to:

(i) Determine nutrition risk; and

(ii) Notify the physician and dietitian of any patients that are at nutrition risk.

(B) Psychiatric, alcohol and drug, and rehabilitation patients shall be rescreened:

(i) Seven (7) days from the initial screen; and

(ii) At least every fourteen (14) days thereafter.

(3) Nutrition care process.

(A) A nutrition assessment of patients at nutrition risk, as reflected in the medical record, shall include as appropriate:

(i) Anthropometric measurements, including:

(a) Height;

(b) Weight;

(c) BMI; and

(d) Goal weight;

(ii) Abnormal pertinent laboratory values;

(iii) The patient's caloric and protein needs;

(iv) Nutrient intake compared to estimated needs;

(v) Determination of:

- (a) Abnormal intake; or
 - (b) Recent weight loss/gain prior to admission;
 - (vi) An objective evaluation of the patient's compliance with a physician-ordered diet prior to admission;
 - (vii) Pertinent food/drug interactions;
 - (viii) An evaluation of the patient's special feeding/nutrient/fluid needs;
 - (ix) Patient's food preferences, dislikes, allergies, or intolerances; and
 - (x) Nutrition summary, including identification of nutrition problems.
- (B) The patient care plan on all patients found to be at nutrition risk shall include the following nutrition components, as appropriate:
 - (i) Individualized nutrition counseling;
 - (ii) Discharge planning;
 - (iii) Comprehensive nutrition assessments to include further clinical, laboratory, social, or nutrition data to assist with the ongoing evaluation;
 - (iv) Follow-up care to evaluate the effectiveness of the nutrition regimen; and
 - (v) Any requests for alterations or modifications to the ordered diet's nutrient content, consistency, administration route/method, or meal pattern as served in the hospital in order to meet the nutrition needs and/or special feeding needs of the patient.

(4) **Nutrition counseling.** Documentation of nutrition counseling shall include:

- (A) Description of the individualized nutrition counseling;
- (B) Objective evaluation of the patient's and/or caregiver's:
 - (i) Understanding; and
 - (ii) Ability to carry out the diet order; and
- (C) Plans for continued counseling and/or recommendations for:
 - (i) Postdischarge counseling; and
 - (ii) Evaluation of patient diet compliance.

(5) Nutrition monitoring and evaluation:

(A)(i) Shall be performed when the patient is at nutrition risk and documented in the medical record.

(ii) The frequency of follow-up nutritional care shall be determined by the patient's condition;

(B) Shall be documented in the patient's medical record on all patients at nutrition risk; and

(C) Shall be documented to include an evaluation of the effectiveness of the prescribed nutrition regimen, changing nutrition status/needs, nutrition counseling and/or recommendations to improve patient nutrition care.

20 CAR § 43-117. Infection prevention and control.

(a) General.

(1) The facility shall develop and use a coordinated process that effectively reduces the risk of endemic and epidemic healthcare-associated infections (HAI) in:

(A) Patients;

(B) Healthcare workers; and

(C) Visitors.

(2)(A) There shall be a comprehensive list of communicable diseases for which:

(i) Patients shall be isolated; and

(ii) There are visitation restrictions.

(B) The list and other policies and procedures for isolation shall conform to the latest edition of the Centers for Disease Control and Prevention, Atlanta, Georgia, guidelines.

(3) It shall be the duty of the administrator or his or her designee to report all infectious or communicable diseases in the facility to the Arkansas Center for Health Statistics of the Department of Health, as required by the Rules Pertaining to Reportable Diseases, 20 CAR pt. 103, Arkansas Code §§ 20-7-109 and 20-7-110, and

Centers for Medicare & Medicaid Services mandatory reporting requirements for Medicare-certified facilities.

- (4) The administrator shall designate a qualified individual who shall:
 - (A) Coordinate the activities of the Infection Prevention and Control Committee;
 - (B) Direct surveillance activities;
 - (C) Ensure policies established by the Infection Prevention and Control Committee are carried out; and
 - (D) Gather and report data regarding the hospital's HAI.
- (5) There shall be policies and procedures establishing and defining the infection prevention and control program to include:
 - (A) Definitions of HAI and communicable diseases based on the current Centers for Disease Control and Prevention or National Healthcare Safety Network surveillance definitions;
 - (B)(i) Performing an annual facility-based risk assessment to determine the infections that are most likely to occur in the facility.
 - (ii) Infections to be addressed include but are not limited to the following:
 - (a) Ventilator-associated event (VAE);
 - (b) Clostridium difficile infection (CDI);
 - (c) Central line-associated bloodstream infection (CLABS);
 - (d) Catheter-associated urinary tract infection (CAUTI); and
 - (e) Use of intravascular catheters.
 - (iii) **Note.** The facility's system for surveillance, calculation, and evaluation of the incidence of HAI within the facility shall conform to the Centers for Disease Control and Prevention's National Healthcare Safety Network or Centers for Disease Control and Prevention publications as applicable;
 - (C) Calculating HAI rates;
 - (D) Measures for assessing and identifying patients and healthcare workers at risk for HAI and communicable diseases;

(E) Methods for obtaining reports of infections and communicable diseases in patients and healthcare workers in a manner and time sufficient to limit the spread of infection;

(F) A plan for monitoring and evaluating at least the following areas or departments to ensure policies and procedures are followed:

- (i) Inpatient and outpatient surgery;
- (ii) Delivery;
- (iii) Nursery;
- (iv) Central sterilization and supply;
- (v) Housekeeping;
- (vi) Laundry;
- (vii) Food and nutrition;
- (viii) Laboratory;
- (ix) Nursing;
- (x) Maintenance;
- (xi) Invasive specialty laboratories (special procedures);
- (xii) Radiology; and
- (xiii) Hemodialysis units;

(G) Measures for prevention of infections including but not limited to:

- (i) Intravenous (IV) devices;
- (ii) Indwelling urinary catheters;
- (iii) Ventilator care;
- (iv) Burns; and
- (v) Immune-suppressed patients;

(H)(i) Measures for prevention of communicable disease outbreaks, especially *Mycobacterium tuberculosis* (TB).

(ii) All plans for the prevention of transmission of TB shall conform to the most current Centers for Disease Control and Prevention Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities;

(I)(i) Isolation procedures and requirements for:

(a) Infected, immune-suppressed patients; and
(b) Patients colonized or infected with resistant organisms;
(ii) Procedures shall conform to the most current Centers for Disease Control and Prevention guidelines;

(J) Provisions for education of patients and their families concerning infections and communicable diseases to include:

- (i) Hand hygiene; and
- (ii) Any isolation precautions;

(K) A plan for monitoring and evaluating all aseptic, isolation, and sanitation techniques employed in the facility to ensure that approved infection prevention and control procedures are followed;

(L) Techniques for:

(i) Hand hygiene, including policies and procedures that reflect facility-selected national guidelines for soap and water as well as alcohol-based hand rub if used;

(ii) Respiratory protection, including policies and procedures that reflect facility-selected national guidelines;

(iii) Asepsis/sterile technique;

(iv) Sterilization;

(v) Sanitary food preparation;

(vi) Disinfection;

(vii) Housekeeping;

(viii) Linen care;

(ix)(a) Liquid and solid waste disposal of both infectious and regular waste.

(b) Disposal of infectious waste shall conform to the latest edition of the Rules Pertaining to the Management of Medical Waste from Generators and Health Care Related Facilities, 20 CAR pt. 53;

(x) Sharps safety;

(xi) Separation of clean from dirty process; and

(xii) Other means of limiting the spread of contagion;
(M) Authority and indications for obtaining microbiological cultures from patients;

(N) Employee health; and

(O) Visitation rules, especially for patients in:

(i) Isolation;

(ii) Critical care;

(iii) Pediatrics; and

(iv) Other special care units, including postpartum care.

(6) There shall be an orientation program for all new healthcare workers concerning:

(A) The importance of infection prevention and control; and

(B) Each healthcare worker's responsibility in the hospital's infection prevention and control program.

(7) There shall be a plan for each employee to receive annual educational programs as indicated based on assessments of the Infection Prevention and Control process.

(8) Maintain a log of documentation of reportable diseases.

(9) No items shall be used past the expiration date.

(b) Infection Prevention and Control Committee.

(1) There shall be a multidisciplinary committee appointed by administration to develop, implement, and monitor direction for the infection prevention and control program based on services impacting the infection prevention and control process.

(2)(A) The medical staff shall appoint a physician to serve as chair of the Infection Prevention and Control Committee.

(B) Additional physician members may be appointed.

(3)(A) The Infection Prevention and Control Committee shall meet at least quarterly.

(B) Minutes of the meetings shall reflect the Infection Prevention and Control Committee's actions in monitoring and directing the hospital's infection prevention and control program.

(4) The Infection Prevention and Control Committee shall fulfill the following responsibilities:

(A) Assist in the development and approval of all infection prevention and control policies and procedures within the facility;

(B) Ensure that an antibiogram is prepared at least annually and compared to the previous one to identify trends;

(C) Monitor any contractual services relative to infection prevention and control (e.g., waste management and laundry) to ensure compliance with all applicable rules;

(D) Review any special infection prevention and control studies conducted within the facility; and

(E) Provide oversight for disinfectants and sterilants.

(c) Employee health.

(1)(A) There shall be policies and procedures for:

(i) Screening healthcare workers for infectious/communicable diseases; and

(ii) Monitoring for healthcare workers exposed to patients with any communicable diseases.

(B) The policies and procedures shall reflect facility-selected national guidelines.

(2)(A) There shall be employee health policies and procedures regarding preventing the transmission of infectious diseases.

(B) The policies and procedures shall reflect facility-selected national guidelines.

(3) There shall be policies that clearly state when healthcare workers shall not render direct patient care.

(4) There shall be a plan for ensuring that:

(A) Each healthcare worker is free from TB; and

(B) The facility follows the latest tuberculosis screening and tuberculosis prevention guidelines approved by the Department of Health Rules Pertaining to Communicable Disease — Tuberculosis, 20 CAR pt. 103.

(5) There shall be a plan for ensuring that all healthcare workers who are exposed to blood and other potentially infectious body fluids are offered immunizations for Hepatitis B.

20 CAR § 43-118. Laboratory.

(a) General.

(1)(A) Each critical access hospital shall provide onsite laboratory services essential to the immediate diagnosis and treatment of patients served by the facility.

(B) Provision shall be made for the following laboratory services:

(i) Chemistry and microscopic examination of urine;

(ii) Complete blood count including:

(a) Hemoglobin;

(b) Hematocrit;

(c) Red blood cells;

(d) White blood cells; and

(e) Platelets;

(iii) Routine chemistry procedures including:

(a) Blood glucose;

(b) Blood urea nitrogen;

(c) Sodium;

(d) Potassium;

(e) Chloride;

(f) Arterial blood gases; and

(g) Cardiac enzyme or enzymes;

(iv) Fecal occult blood;

(v) Pregnancy tests;

(vi) Primary culturing for transmittal to a certified laboratory; and
(vii) Procurement, safekeeping, and transfusion of blood or blood products on an emergency basis:

(a) Either directly; or

(b) Through written arrangement with another facility.

(2) The requirements of the most current rule of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, shall be met.

(3)(A) All laboratory testing that is performed at any site owned and/or operated by the facility shall be approved in writing by the governing body.

(B) The governing body shall authorize the director of the hospital laboratory to provide oversight of all testing to ensure the quality of the laboratory services provided.

(C) A comprehensive list of all testing sites shall be made available to the medical staff.

(4) A laboratory shall refer specimens for testing only to a laboratory possessing a valid Clinical Laboratory Improvement Amendments of 1988 certificate authorizing the performance of testing in the specialty or subspecialty of service for the level of complexity in which the referred test is categorized.

(5) Only results from the critical access hospital laboratory or from other approved laboratories, as determined by hospital policy, shall be placed in the patient's medical record.

(6) Laboratory tests shall be authorized by a physician or other persons authorized by the medical staff and the governing body to order laboratory examinations.

(7) The laboratory shall maintain accurate counts of total patient procedures for each specialty in which tests are performed.

(8) Current reference material such as textbooks shall be available for every laboratory category in which tests are performed.

(9) The laboratory shall make available to the medical staff a list of all tests performed onsite, including the reference range for each test.

(b) **Personnel.**

(1) A member of the medical staff shall be appointed to act as a liaison between the laboratory and the medical staff.

(2)(A) The laboratory shall be under the oversight of a pathologist who is board-certified or eligible.

(B) A pathologist who is not based at the hospital shall:

- (i) Make at least a monthly visit; and
- (ii) Submit a monthly written report to the hospital administrator.

(C) **Note.** A hospital that provides only limited laboratory services (e.g., blood gas laboratory only) shall not be subject to the requirement of oversight of a pathologist.

(3)(A) The laboratory director, as defined by the Clinical Laboratory Improvement Amendments of 1988, shall be responsible for the overall operation of the laboratory but may delegate specific responsibilities to supervisory personnel.

(B) However, the director remains responsible for ensuring that all duties are properly performed and documented.

(C) The laboratory director shall be responsible for the following:

(i) Ensuring that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance which includes the preanalytic, analytic, and postanalytic phases of testing;

(ii) Ensuring that the physical plant and environmental conditions of the laboratory:

(a) Are appropriate for the testing performed; and

(b) Provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(iii) Ensuring that:

(a) The test methodologies selected have the capability of providing the quality of results required for patient care;

(b) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(c) Laboratory personnel are performing the test methods as required for accurate and reliable results;

(iv) Ensuring that the laboratory is enrolled in a proficiency testing program approved by the United States Department of Health and Human Services for the testing performed and that:

(a) The proficiency testing samples are tested in the same manner as the patient samples;

(b) The results are returned within the time frames established by the proficiency testing program;

(c) All proficiency testing reports are reviewed by the appropriate staff to:

(1) Evaluate the laboratory's performance; and

(2) Identify any problems that require corrective action; and

(d) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

(v) Ensuring that the quality control and quality assurance/performance improvement programs are established and maintained to:

(a) Ensure the quality of laboratory services provided; and

(b) Identify failures in quality as they occur;

(vi) Ensuring the establishment and maintenance of acceptable levels of analytical performance for each test system;

(vii) Ensuring that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified and that patient test results are reported only when the system is functioning properly;

(viii) Ensuring that reports of test results include pertinent information required for interpretation;

(ix) Ensuring that consultation is available to the laboratory's clients and to the medical staff on matters relating to:

(a) The quality of the test results reported; and

(b) Interpretation concerning specific patient conditions;

(x) Ensuring there is a sufficient number of laboratory personnel with the appropriate education and either training or experience to:

(a) Provide appropriate consultation, properly supervise, and accurately perform tests; and

(b) Report test results;

(xi) Ensuring all personnel have the appropriate education and experience, receive the appropriate training for the type of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(xii) Ensuring there is documentation of training for laboratory personnel who perform special procedures such as arterial punctures and therapeutic phlebotomies;

(xiii) Ensuring that qualified testing personnel are on duty or on call at all times;

(xiv)(a) Ensuring that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

(b) The procedures for evaluation of the competency of the staff shall include but are not limited to the following:

(1) Direct observations of routine patient test performance, including:

(A) Patient preparation, if applicable; and

(B) Specimen handling, processing, and testing;

- (2) Monitoring the recording and reporting of test results;
- (3) Review of:
 - (A) Intermediate test results or worksheets;
 - (B) Quality control records;
 - (C) Proficiency testing results; and
 - (D) Preventive maintenance records;
- (4) Direct observation of performance of instrument maintenance and function checks;
- (5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples;
- (6) Assessment of problem-solving skills; and
- (7) Evaluation and documentation of the performance of all personnel with at least the following frequency:
 - (A) Semiannually during the first year of employment in the laboratory;
 - (B) Annually after the first year; and
 - (C) Prior to reporting patient test results if test methodology or instrumentation changes;
- (xv) Ensuring that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;
- (xvi) Ensuring there is:
 - (a) A plan for providing continuing education for the laboratory staff; and
 - (b) Documentation of each employee's participation;
- (xvii) Specifying the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing; and
- (xviii) Specifying the examinations and procedures each individual is authorized to perform, whether:

(a) Supervision is required for specimen processing, test performance, or result reporting; and

(b) Supervisory or director review is required prior to reporting patient test results.

(4) There shall be a supervisor accessible at all times when testing is performed.

(5) Personnel responsible for day-to-day supervision of the laboratory shall meet at least one (1) of the following qualifications:

(A) A bachelor's degree in medical technology from an accredited institution and at least one (1) year of clinical laboratory training or experience relative to the specialties being supervised;

(B) A bachelor's degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution with at least two (2) years of clinical laboratory training or experience relative to the specialties being supervised;

(C) An associate degree in a laboratory science or medical laboratory technology from an accredited institution with at least two (2) years of clinical laboratory training or experience relative to the specialties being supervised;

(D) A passing score on the Clinical Laboratory Technology Proficiency examination approved by the United States Department of Health and Human Services and at least six (6) years of clinical laboratory experience with at least two (2) years of experience relative to the specialties being supervised; or

(E) Employment as a laboratory supervisor prior to January 1, 1995, in a hospital licensed by the Department of Health.

(6) Testing personnel shall meet at least the following qualifications:

(A) Have earned a high school diploma or equivalent; and

(B)(i) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

(ii) Such training shall ensure that the individual has the following:

(a) Skills required for proper patient preparation and specimen collection, to include the following:

- (1) Labeling;
 - (2) Handling;
 - (3) Preservation or fixation;
 - (4) Processing or preparation; and
 - (5) Transportation and storage;
- (b) The skills required for implementing all standard laboratory procedures;
- (c) The skills required for:
 - (1) Performing each test method; and
 - (2) Proper instrument use;
- (d) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
- (e) A working knowledge of reagent stability and storage;
- (f) The skills required to implement the quality control policies and procedures of the laboratory;
- (g) An awareness of the factors that influence test results; and
- (h) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting test results.

(c) Procedure manual.

(1)(A) There shall be a procedure manual for the performance of all analytical methods used by the laboratory readily available and followed by laboratory personnel.

(B) Textbooks may be used as supplements but shall not be used in lieu of the laboratory's written procedures for testing or examining specimens.

(C) The procedure manual shall include, when applicable to the test procedure, the following:

- (i) Requirements for patient preparation, specimen collection and processing, labeling, preservation, and transportation, including criteria for specimen rejection;

(ii) Procedures for microscopic examinations, including the detection of inadequately prepared slides;

(iii) Step-by-step performance of the procedure, including test calculations and interpretation of results;

(iv) Preparation of:

(a) Slides;

(b) Solutions;

(c) Calibrators;

(d) Controls;

(e) Reagents;

(f) Stains; and

(g) Other materials used in testing;

(v) Calibration and calibration verification procedures;

(vi) The reportable range for patient test results as verified by the laboratory;

(vii) Quality control procedures for each test to include the following:

(a) Type of control;

(b) Identity of control;

(c) Number of controls;

(d) Frequency of testing controls; and

(e) Criteria for determining acceptability of control results;

(viii) Remedial actions to be taken when any of the following occur:

(a) Calibration results are unacceptable;

(b) Control results are unacceptable;

(c) Equipment or test methodologies fail;

(d) Patient test values are outside the laboratory's reportable range of patient test results;

(e) The laboratory cannot report patient test results within its established time frames; and

(f) Errors in reported patient test results are detected;

(ix) Limitations in methodologies, including interfering substances;
(x) Reference ranges (normal values);
(xi) A list of "panic values" with written instructions for reporting such values;

(xii) Pertinent literature references;
(xiii) Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;
(xiv) The laboratory's system for reporting patient test results;
(xv) Description of the course of action to be taken in the event that a test system becomes inoperable; and

(xvi) Criteria for the referral of specimens, including procedures for:
(a) Specimen submission and handling; and
(b) Recordkeeping.

(2) The procedure manual shall be reviewed, approved, signed, and dated by:
(A) The current director of the laboratory; or
(B) An individual designated by the director in compliance with the Clinical Laboratory Improvement Amendments of 1988 requirements.

(3) Each revision or addition to the procedure manual shall be reviewed, approved, signed, and dated by:

(A) The current director of the laboratory; or
(B) An individual designated by the director in compliance with the Clinical Laboratory Improvement Amendments of 1988 requirements.

(4) The laboratory shall maintain a copy of each discontinued procedure for two (2) years with the dates of initial use and discontinuance.

(d) **Record system.**

(1)(A) The laboratory shall have policies and procedures for a record system that shall ensure positive identification of patient specimens from the time of specimen collection until the time of test completion and results reporting.

(B) The record system shall include provisions for test:

(i) Requisitions;

- (ii) Records; and
- (iii) Reports.

(C) The configuration of the system may be established by the laboratory provided all of the required information is readily retrievable for at least two (2) years.

(2) The laboratory shall perform tests at the written or electronic request of an authorized person.

(3) Records of test requisitions or test authorizations shall be retained for a minimum of two (2) years.

(4) The test requisition shall include:

(A) Identification of the patient;

(B) The name of the authorized person who ordered the test;

(C) The test or tests requested;

(D) The date the test is to be performed;

(E) For Pap smears, the patient's:

(i) Last menstrual period;

(ii) Age or date of birth; and

(iii) Indication of whether the patient had a previous abnormal report, treatment, or biopsy; and

(F)(i) Any additional information relevant and necessary to a specific test to ensure accurate and timely testing and reporting of results.

(ii) Examples:

(a) Age;

(b) Sex;

(c) Current medications;

(d) Time of specimen collection;

(e) Diagnosis;

(f) Type of specimen; and

(g) Fasting.

(5)(A) Records of patient testing, including instrument printouts, shall be retained for at least two (2) years.

(B) Immunohematology records and transfusion records shall be retained for at least five (5) years.

(C) **Exception.** If an instrument is interfaced with a computer and the electronic data cannot be edited, the instrument printouts do not have to be retained.

(6) Test records shall provide documentation of the information required for test requisitions as well as the following information:

- (A) Unique identification of the patient specimen;
- (B) The date and time of specimen receipt into the laboratory;
- (C) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability;
- (D) The tests and date of performance of each;
- (E) The time of completion of testing; and
- (F) The identity of the person who performs each test.

(7) The laboratory report shall be sent promptly to the authorized person who requested the test.

(8)(A) A duplicate of each test report, including both preliminary and final reports, shall be retained for at least two (2) years.

(B) The duplicate may be retained electronically as long as it contains the exact information sent to the individual:

- (i) Ordering the test; and
- (ii) Utilizing the test results.

(C) For test reports requiring an authorized signature or containing personnel identifiers, the exact duplicate must include the signature or identifiers.

(D) Immunohematology reports shall be retained for at least five (5) years, and pathology reports shall be retained for at least ten (10) years.

(9) The test report shall include the following:

- (A) Identification of the patient;
- (B) Date of specimen collection;
- (C) The test or tests performed;
- (D) Test results and, if applicable, the units of measurement;

(E) Date results were reported;
(F) The condition and disposition of specimens that do not meet the laboratory's criteria for acceptability; and

(G)(i) Any additional information relevant and necessary for the interpretation of the results of a specific test.

(ii) Examples:

- (a) Type of specimen;
- (b) Time of specimen collection; and
- (c) Fasting.

(10) The laboratory shall have policies and procedures for referring patient specimens to reference laboratories, to include:

(A) Current list of reference laboratories with the following information:

- (i) Clinical Laboratory Improvement Amendments of 1988 number;
- (ii) Specialties and subspecialties in which the laboratory is certified;

and

(iii) Expiration date of the Clinical Laboratory Improvement Amendments of 1988 certificate;

(B) Specimen submission and handling; and

(C) Recordkeeping system.

(11) The laboratory shall not revise results or information directly related to the interpretation of results provided by a reference laboratory.

(12)(A) The laboratory shall retain an exact duplicate of each reference laboratory report, including each preliminary and corrected report, for at least two (2) years.

(B) Pathology reports from reference laboratories shall be retained for ten (10) years, and immunohematology reports shall be retained for five (5) years.

(13) The laboratory's report shall indicate the:

(A) Test or tests performed by a reference laboratory; and

(B) Name and address of each laboratory location at which a test was performed.

(e) General quality control.

(1) The laboratory shall be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of testing.

(2) The laboratory shall have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the:

(A) Type and volume of testing performed; and

(B) Maintenance of quality during all phases of testing.

(3) The manufacturer's instructions shall be followed when using an:

(A) Instrument;

(B) Kit; or

(C) Test system.

(4) Components of reagent kits of different lot numbers shall not be interchanged unless otherwise specified by the manufacturer.

(5)(A) The laboratory shall define criteria for those conditions that are essential for:

(i) Proper storage of reagents and specimens; and

(ii) Accurate and reliable:

(a) Test system operation; and

(b) Test result reporting.

(B)(i) These conditions shall include, if applicable, water quality, temperature, humidity, and protection of equipment and instrumentation from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

(ii) There shall be documentation of the remedial actions taken to correct problems with these conditions.

(6) Reagents, solutions, culture media, control materials, calibration materials, and other supplies as appropriate shall be labeled to indicate the following:

(A) Identity, and, when significant:

(i) Titer;

(ii) Strength; or

- (iii) Concentration;
- (B) Recommended storage requirements;
- (C) Preparation and expiration dates; and
- (D) Other pertinent information required for proper use.

(7) Reagents, solutions, culture media, control materials, calibration materials, and other supplies shall be prepared, stored, and handled in a manner to ensure that they are not used when:

- (A) The expiration date has been exceeded; or
- (B) They have deteriorated or are of substandard quality.

(8)(A) The laboratory shall comply with the Food and Drug Administration:

(i) Product dating requirements of 21 C.F.R. § 610.53 for blood, blood products, and other biologicals; and

(ii) Labeling requirements in 21 C.F.R. § 809.10 for all other in vitro diagnostics.

(B) Any exception to the product dating requirements in 21 C.F.R. § 610.53 shall be granted by the Food and Drug Administration in the form of an amendment of the product license in accordance with 21 C.F.R. § 610.53(d).

(C) All exceptions shall be documented by the laboratory.

(9) Test methodologies and equipment shall be selected and testing performed in a manner that provides test results within the laboratory's stated performance specifications for each test.

(10)(A) Before the laboratory reports patient test values using a new method or device, it shall first verify or establish for each method the performance specifications for the following performance characteristics, as applicable:

- (i) Accuracy;
- (ii) Precision;
- (iii) Analytical sensitivity and specificity, to include interfering substances;
- (iv) Reportable range of patient test results;
- (v) Reference range (normal values); and

(vi) Any other performance characteristics required for test performance.

(B) The laboratory shall:

(i) Have documentation of the verification or establishment of all applicable test performance specifications; and

(ii) Establish control and calibration procedures based upon those specifications.

(11)(A) The laboratory shall perform maintenance and function checks for all equipment, instruments, and test systems according to the manufacturers' instructions.

(B) If the manufacturer does not define maintenance or function checks, the laboratory shall establish protocols ensuring equipment, instruments, or test systems perform accurately and reliably.

(C) Maintenance and function checks shall be performed with at least the frequency of the manufacturer's instructions.

(12)(A) All function checks and maintenance activities shall be documented.

(B) The function checks shall be within the laboratory's or manufacturer's established limits before patient testing is conducted.

(13) For each method or device, the laboratory shall perform calibration procedures:

(A) At a minimum:

(i) In accordance with manufacturer's instructions, if provided;

(ii) Using calibration materials provided as specified, as appropriate;

and

(iii) With at least the frequency recommended by the manufacturer;

(B) In accordance with established laboratory criteria to include:

(i) The number, type, and concentration of calibration materials, acceptable limits for calibration, and the frequency of calibration; and

(ii) Using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value; and

(C) Whenever calibration verification fails to meet the laboratory's established acceptable limits for calibration verification.

(14) For each method or device, the laboratory shall perform calibration verification procedures:

(A) At a minimum, in accordance with the manufacturer's instructions, if provided; and

(B) In accordance with established laboratory criteria to include:

(i) The number, type, and concentration of calibration materials, acceptable limits for calibration verification, and frequency of calibration verification;

(ii) Calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value;

(iii) Verification of the laboratory's established reportable range of patient test results which shall include at least a:

(a) Minimal or zero (0) value;

(b) Midpoint value; and

(c) Maximum value at the upper limit of that range; and

(iv) Performance of calibration verification at least every six (6) months or when the following occur:

(a) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results and control values are not adversely affected by reagent lot number changes;

(b) There is a major preventive maintenance or replacement of critical parts that may influence test performance;

(c) Controls reflect an unusual trend or shift or are outside the laboratory's acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem; and

(d) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification than specified by the manufacturer.

(15) All calibration and calibration verification activities shall be documented.

(16) **Control procedures.**

(A) Controls shall be performed as defined or as otherwise defined under a specific category heading.

(B)(i) For each device, the laboratory shall:

(a) Evaluate instrument and reagent stability and operator variance in determining the number, type, and frequency of testing calibration or control materials; and

(b) Establish criteria for acceptability used to monitor test performance during a run of patient specimen or specimens.

(ii) A run is an interval within which the accuracy and precision of a testing system is expected to be stable, but it cannot be:

(a) Greater than twenty-four (24) hours; or

(b) Less than the frequency recommended by the manufacturer.

(iii) For each procedure, the laboratory shall monitor test performance using:

(a) Calibration materials;

(b) Control materials; or

(c) A combination thereof.

(iv) Controls shall be performed as follows:

(a)(1) For qualitative tests, the laboratory shall include a positive and a negative control with each run of patient specimens.

(2) Internal procedural controls, both positive and negative, may be used to satisfy this requirement;

(b) For quantitative tests, the laboratory shall include at least two (2) samples of different concentrations of either calibration materials, control materials, or a combination thereof with the frequency not fewer than two (2) levels per twenty-four (24) hours of operation;

(c) If calibration and control materials are not available, the laboratory shall have an alternative mechanism to ensure the validity of patient test results;

(d) Control samples shall be tested in the same manner as patient test specimens; and

(e)(1) When calibration or control materials are used, statistical parameters (e.g., mean and standard deviation) for each lot number of calibration or control material shall be determined through repetitive testing.

(2) Levey-Jennings plots or other visual representation methods shall be used to evaluate statistical data for trends and shifts.

(3) Weekly supervisory review is required.

(4) Control values shall be evaluated as follows:

(A) The stated values of assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory and are verified by the laboratory;

(B) Statistical parameters for unassayed materials shall be established over time by the laboratory through concurrent testing with calibration materials or control materials having previously determined statistical parameters; and

(C) Control results shall meet the laboratory's criteria for acceptability prior to reporting patient test results.

(17)(A) The laboratory shall document all control activities.

(B) Documentation shall be retained for a period of two (2) years.

(C) Immunohematology quality control records shall be retained for a period of five (5) years.

(D) Cytology and histopathology quality control records shall be retained for a period of ten (10) years.

(f) **Chemistry.**

(1) The following requirements apply only to blood gas analysis, regardless of the testing site:

(A) Follow the manufacturer's instructions regarding calibration of the blood gas analyzer;

(B) Test at least one (1) level of control material each eight (8) hours of patient testing;

(C) Rotate the order in which the controls are performed so that normal, alkalosis, and acidosis levels are tested; and

(D) Test one (1) sample of calibration material or control material each time patients are tested if the instrument does not internally verify calibration at least every thirty (30) minutes.

(2) For electrophoretic determinations:

(A) At least one (1) control sample shall be used in each electrophoretic cell; and

(B) The control sample shall contain fractions representative of those routinely reported in the patient specimens.

(g) Hematology.

(1) There shall be at least two (2) levels of controls for nonmanual hematology testing systems every eight (8) hours in which patient testing is performed.

(2) There shall be at least one (1) level of control for manual cell counts every eight (8) hours in which patient testing is performed.

(3)(A) Manual cell counts shall be performed in duplicate with documentation of both counts.

(B) The laboratory shall establish criteria for the acceptable difference between duplicate counts.

(4) There shall be two (2) levels of controls for nonmanual coagulation testing systems:

(A) Every eight (8) hours in which patient testing is performed; and

(B) Each time a change in reagents occurs.

(5) Each individual shall test two (2) levels of controls:

(A) Before performing manual coagulation testing on patient samples; and

(B) Each time a change in reagents occurs.

(6)(A) Manual coagulation tests on both patient and control specimens shall be performed in duplicate with documentation of both times.

(B) The laboratory shall establish criteria for the acceptable difference between duplicate times.

(7) Background counts of diluents shall be performed daily and results recorded.

(8) If the microhematocrit centrifuge is used, the maximum packing time shall be determined at least every six (6) months.

(9) The laboratory director shall establish written criteria for abnormal cell morphology requiring review by a qualified physician who is board-certified or board-eligible in either pathology or hematology.

(10) The laboratory shall maintain a file of unusual hematology slides to be used in the orientation, training, and continuing education of laboratory personnel.

(h) **Immunology.**

(1) The equipment, glassware, reagents, controls, and techniques for tests for syphilis shall conform to manufacturers' specifications.

(2)(A) The laboratory shall run serologic tests on patient specimens concurrently with:

(i) A positive serum control of known titer; or

(ii) Controls of graded reactivity plus a negative control.

(B)(i) If patient results are reported in terms of graded reactivity, controls of graded reactivity shall be used.

(ii) If patient results are reported as a titer, controls of known titer shall be used with results reported as a titer.

(3) The laboratory shall employ controls that evaluate all phases of the test system to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient.

(4) A facility manufacturing blood and blood products for transfusion or serving as a referral laboratory for such a facility shall meet the following:

(A) Syphilis serology testing requirements of 21 C.F.R. § 606.65(c) and (e) and 21 C.F.R. § 640.5(a);

(B) HIV testing requirements of 21 C.F.R. § 610.45; and

(C) Hepatitis testing requirements of 21 C.F.R. § 610.40.

(i) **Immunohematology.**

(1) There shall be provision for prompt ABO blood grouping, D(Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility that is certified in immunohematology, transfusion services, and blood banking under the Clinical Laboratory Improvement Amendments of 1988.

(2)(A) If the facility does not provide immunohematological or blood banking services onsite, there shall be a written agreement with an outside laboratory or blood bank that governs the procurement, transfer, and availability of blood and blood products.

(B) The agreement shall be reviewed and approved by the laboratory director.

(3) The laboratory shall perform and document ABO group and D(Rho) typing on all donor red cells received from outside sources prior to transfusing.

(4) The laboratory shall perform ABO group and D(Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing in accordance with:

(A) Manufacturers' instructions, if provided; and

(B) As applicable, with 21 C.F.R. pt. 606 (with the exception of 21 C.F.R. § 606.20.a, Personnel) and 21 C.F.R. § 640 et seq.

(5)(A) The laboratory shall perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents.

(B) For confirmation of ABO group, the unknown serum shall be tested with known A1 and B red cells.

(C) All reactions shall be documented.

(6) The laboratory shall determine the D(Rho) type by testing and documenting the reaction of unknown red cells with anti-D(Rho) blood grouping reagent.

(7) If required in the manufacturer's package insert for anti-D(Rho) reagents, the laboratory shall employ a control system (Rh-hr control) capable of detecting false positive D(Rho) test results.

(8) Each day of use the laboratory shall perform and document the following quality control checks for each vial of antisera and reagent red cells:

(A) Positive control only for:

(i) ABO antisera;

(ii) ABO reagent red cells; and

(iii) Antibody screening cells (at least one (1) known antibody); and

(B) Positive and negative controls for:

(i) D(Rho) antisera;

(ii) Other antisera; and

(iii) Antihuman globulin (Coombs serum).

(9) Records shall identify the source and lot number of each reagent on each day of use.

(10) Policies and procedures to ensure positive identification of a blood or blood product recipient shall be established and followed.

(11) Donor blood and blood products shall be stored or maintained for transfusion under conditions required to prevent deterioration and to ensure optimum integrity, whether in:

(A) The blood bank; or

(B) A remote storage refrigerator.

(12) Donor blood shall be stored in a refrigerator that meets the following criteria:

(A) The refrigerator shall be connected to an emergency power source;

(B) An audible alarm system shall:

(i) Monitor proper storage temperature; and

- (ii) Sound at a location that is staffed twenty-four (24) hours per day;
 - (C) The refrigerator shall not be used for the storage of hazardous or contaminated items;
 - (D) The refrigerator shall have adequate space to provide for segregated storage of the following:
 - (i) Donor blood prior to completion of tests;
 - (ii) Donor blood not suitable for use; and
 - (iii) Autologous units; and
 - (E) A temperature recorder shall be connected to the refrigerator.
- (13)(A) The high and low activation temperatures of the alarm system shall be checked and documented at least quarterly.
- (B) The response to the activated alarm shall be documented.
- (14)(A) The temperature recorder shall be compared daily to a thermometer in the refrigerator.
- (B) Results of the temperature checks shall be documented.
- (15) The temperature recorder chart shall be changed weekly, and the individual who changes the chart shall initial and date it.
- (16)(A) Written criteria shall be established for daily inspection of the blood storage unit for:
- (i) Outdated blood;
 - (ii) Hemolysis;
 - (iii) Bacterial contamination; and
 - (iv) Unit integrity.
- (B) Blood shall be visually inspected at the time of issue.
- (C) Results of all inspections shall be recorded.
- (17) Records shall be maintained of all blood or blood components:
- (A) Received;
 - (B) Crossmatched;
 - (C) Transfused;
 - (D) Expired; or

(E) Returned to the supplier.

(18) Patient's serum less than seventy-two (72) hours old shall be used in the compatibility procedure.

(19)(A) All blood for transfusions, except for autologous transfusions, shall be tested for hepatitis and for HIV antibodies before it is transfused.

(B) The tests for hepatitis and/or HIV antibodies may be performed by the:

(i) Supplier; or

(ii) Institution in which the blood is transfused.

(20) Samples of both patient and donor blood shall be retained at least seven (7) days following transfusion.

(21)(A) Procedures shall be established for the prompt investigation of all suspected transfusion reactions.

(B) The laboratory director shall review all suspected transfusion reactions and a report shall be given to a committee of the medical staff.

(22) Criteria shall be established for the reissuing of donor blood to ensure that the blood has been maintained under conditions required to ensure the safety of individuals being transfused within the facility.

(23)(A) Records of therapeutic phlebotomies shall be maintained, detailing the:

(i) Patient name;

(ii) Date;

(iii) Time;

(iv) Amount drawn;

(v) Phlebotomist; and

(vi) Disposition of the blood.

(B) Blood drawn as a therapeutic phlebotomy shall not be used for transfusion.

(24) A committee of the medical staff shall fulfill the following responsibilities:

(A) Establish criteria for the proper use of blood and its components;

(B) Monitor the transfusion of blood and its components to ensure the established criteria for proper use are met;

(C) Review the reports of suspected transfusion reactions; and

(D) Establish criteria for therapeutic phlebotomies.

(25) Blood banking policies and procedures shall conform to the current Standards for Blood Banks and Transfusion Services of the American Association of Blood Banks.

(j) Urinalysis.

(1) Routine urinalysis shall be performed within two (2) hours of collection of the specimen unless the specimen is refrigerated.

(2) Manufacturers' instructions shall be followed for all tests.

(3) Two (2) levels of controls shall be performed and documented each day of patient testing utilizing an automated strip reader.

(4) A refractometer for measuring urine specific gravity shall be checked each day of use with a low-level (1.000) and upper-level standard or control.

(k) Microbiology.

(1)(A) Each day of use, the laboratory shall evaluate the detection phase of direct antigen systems using an appropriate positive and negative control organism or antigen extract.

(B) When direct antigen systems include an extraction phase, the system shall be checked each day of use using a positive organism.

(2) The laboratory shall check each batch or shipment of reagents, discs, stains, antisera, and identification systems (systems using two (2) or more substrates) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

(3) Unless otherwise specified, each day of use the laboratory shall test staining materials for intended reactivity to ensure predictable staining characteristics.

(4) The laboratory shall check fluorescent stains for positive and negative reactivity each time of use unless otherwise specified.

(5)(A) The laboratory shall check each batch or shipment of media for sterility if:

- (i) It is intended to be sterile; and
- (ii) Sterility is required for testing.

(B) Media shall be checked for its ability to support growth and, as appropriate, selectivity/inhibition and/or biochemical response.

(6)(A) The laboratory may use the manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the National Committee for Clinical Laboratory Standards (NCCLS) for media quality control.

(B) The laboratory shall:

- (i) Document that the physical characteristics of the media are not compromised; and
- (ii) Report any deterioration of the media to the manufacturer.

(7) The laboratory shall:

- (A) Follow the manufacturer's specifications for using the media; and
- (B) Be responsible for the test results.

(8) The following media shall be retested using NCCLS standards for growth, inhibition, and selectivity, as applicable:

- (A) Campylobacter agar;
- (B) Media for the selective isolation of pathogenic Neisseria;
- (C) Media used to isolate parasites, viruses, Mycoplasma, Chlamydia;
- (D) Mueller-Hinton media used for antimicrobial susceptibility tests; and
- (E) Media commercially prepared and packaged as a unit or system consisting of two (2) or more different substrates, primarily used for microbial identification.

(9) The laboratory shall check positive and negative reactivity with control organisms as follows:

- (A) Each day of use for:
 - (i) Catalase, coagulase, beta-lactamase, and oxidase reagents; and

- (ii) DNA probes;
- (B) Each week of use for:
 - (i) Gram and acid-fast stains; and
 - (ii) Bacitracin, optochin, ONPG, X and V discs or strips;
- (C) Each month of use for antisera;
- (D) Each week of use the laboratory shall check XV discs or strips with a positive control; and
- (E) For antimicrobial susceptibility tests, the laboratory shall check each new batch of media and each lot of antimicrobial discs or wells before or concurrent with initial use using approved reference organisms:
 - (i) The laboratory's zone sizes or minimum inhibitory concentrations (MIC) for reference organisms shall be within established limits before reporting patient test results; and
 - (ii)(a) Each day tests are performed the laboratory shall use the appropriate control organisms to check the procedure unless adequate precision can be demonstrated.
 - (b) Once adequate precision is demonstrated, the controls may be performed each week of use.
 - (c) Documentation of precision studies is required.
- (10)(A) Antibiotic sensitivities shall be performed using a recognized method.
- (B) If the Kirby-Bauer method is utilized:
 - (i) Proper-sized petri dishes shall be used;
 - (ii) Disc zone sizes shall be measured and recorded, or a template shall be used; and
 - (iii) A standardized inoculum shall be used.
- (11) Records shall reflect all tests used to isolate and identify organisms.
- (12) For laboratories performing mycobacteriological testing, the laboratory shall:
 - (A)(i) Each day of use, check the iron uptake test with at least one (1) positive and one (1) negative acid-fast control organism.

(ii) Check all other reagents or test procedures used for identification with at least a positive acid-fast control organism;

(B) Each week of use, check the fluorochrome acid-fast stain's reactivity with a positive and a negative control organism;

(C) Each week of use, check the acid-fast stain's reactivity with a positive control organism; and

(D) Each week of use, check the procedure for susceptibility tests performed on *Mycobacterium tuberculosis* isolated with a strain of *Mycobacterium tuberculosis* susceptible to all antimycobacterial agents tested.

(13) For laboratories conducting mycological testing, the laboratory shall:

(A) Each day of use, if using the auxanographic medium for nitrate assimilation, check the nitrate reagents with a peptone control;

(B) Each week of use, check the acid-fast stain's reactivity with a positive and a negative control organism; and

(C) Each day of use:

(i) Test each drug for susceptibility tests with at least one (1) control strain that is susceptible to the drug; and

(ii) Ensure that patient test results are reported only when control results are within the laboratory's established control limits.

(14) For laboratories performing parasitology tests, the laboratory shall:

(A) Have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens;

(B)(i) Calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites if size is a critical parameter.

(ii) Calibration of the micrometer shall be checked:

(a) Annually; or

(b) After microscope repair or major maintenance.

(iii) Documentation of the calibration is required; and

(C) Check permanent stains each month of use using a fecal sample control that will demonstrate staining characteristics.

(15) For laboratories performing virology tests, the laboratory shall:

(A) Have available host systems for the isolation of viruses and identification methods that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered;

(B) Maintain records that reflect the systems used and the reactions observed; and

(C) Simultaneously culture, for identification tests, uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.

(16)(A) A microbiological safety cabinet shall be used when mycobacteriology or mycology cultures are manipulated.

(B) The cabinet shall meet the following special requirements:

(i) Have a face velocity of at least seventy-five (75) feet per minute;

(ii) Be connected to an independent exhaust system;

(iii) Have filters with ninety-nine and ninety-seven hundredths percent (99.97%) efficiency, based on the dioctylphthalate (DOP) test method, in the exhaust system;

(iv) Be designed and equipped to permit the safe removal, disposal, and replacement of contaminated filters; and

(v) Be provided with a means of disinfection.

(17) Mycology, mycobacteriology, or virology cultures shall be disinfected prior to leaving the control of the laboratory.

(I) Pathology — Histopathology and cytology.

(1) The ventilation system shall be adequate to properly remove vapors, fumes, and excessive heat.

(2) Staining dishes shall be properly labeled and covered when not in use.

(3) Flow charts that reflect the staining procedure used shall be available.

(4)(A) A control slide of known reactivity shall be included with each slide or group of slides for differential or special stains.

(B) Reaction of the control slide with each special stain shall be documented.

(5) For cytology stains:

(A) All gynecologic smears shall be stained using a Papanicolaou (Pap) or modified Pap staining method;

(B) Effective measures shall be taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process; and

(C) Nongynecologic specimens that have a high potential for cross-contamination shall be stained separately from other nongynecologic specimens and the stains shall be filtered or changed following staining.

(6) All cytology slide preparations shall be retained for five (5) years.

(7) For histopathology:

(A) All stained slides shall be retained at least ten (10) years;

(B) All specimen blocks shall be retained at least two (2) years; and

(C) All remnants of tissue specimens shall be retained in a manner that ensures proper preservation of the tissue specimens until:

(i) The portions submitted for microscopic examination have been examined; and

(ii) A diagnosis has been made.

(8) An exact duplicate of each test report shall be retained for at least ten (10) years.

(9)(A) The following reports shall be signed to reflect the review of a board-certified pathologist, or, as applicable, another individual meeting the qualifications specified in the Clinical Laboratory Improvement Amendments of 1988 requirements:

(i) All tissue pathology reports;

(ii) All nongynecologic cytology reports; and

(iii) All gynecologic cytology reports on smears containing cells

exhibiting:

(a) Reactive or reparative changes;

(b) Atypical squamous/glandular cells; or

(c) Premalignant or malignant condition.

(B) **Note.** If an electronic signature is used, the laboratory shall ensure that only the authorized person can release the signature.

(C) Refer to 20 CAR § 43-113, Health Information Services.

(10) The laboratory shall:

(A) Compare clinical information, when available, with cytology reports;

(B) Compare each malignant and premalignant gynecology report with the histopathology report, if available; and

(C) Determine the causes of any discrepancies.

(11)(A) All tissues surgically removed shall be examined by an anatomic pathologist.

(B) The medical staff shall develop a list of tissues that need not be examined.

(12)(A) A frozen section diagnosis, as reported to the surgeon, shall be documented and signed by the pathologist at the time the frozen section is performed.

(B) The documentation may be on:

(i) The requisition;

(ii) A patient test log; or

(iii) A report form.

(13) Autopsy services shall be under the supervision of a board-certified pathologist.

(14)(A) Autopsy findings in a complete protocol shall be filed in the patient's medical record within sixty (60) days of the autopsy.

(B) A provisional anatomical diagnosis shall be recorded within seventy-two (72) hours after autopsy.

(C) A duplicate copy of the autopsy report shall be maintained in the laboratory autopsy file.

(m) **Radiobioassay.**

(1) Background checks shall be performed each day at the proper window setting for each type of isotope being used, as applicable.

(2) Criteria for unacceptable changes in background levels shall be established.

(3)(A) Safety precautions shall be written and appropriately displayed.

(B) Film badges and/or rings shall be worn, as applicable.

(4) There shall be written procedures to ensure:

(A) Reliability of testing; and

(B) Safety of patients and personnel.

(5) All procedures for safety and disposal of radioactive waste shall conform to the most current Rules for Control of Sources of Ionizing Radiation, 20 CAR pt. 3, adopted and promulgated by the State Board of Health.

(n) **Quality assurance/performance improvement.**

(1)(A) Each laboratory shall establish a quality assurance/performance improvement plan.

(B) The plan shall follow written policies and procedures for a comprehensive program that monitors and evaluates the ongoing and overall quality of the total testing process.

(C) The plan shall:

(i) Evaluate the effectiveness of the laboratory's policies and procedures;

(ii) Identify and correct problems;

(iii) Ensure the accurate, reliable, and prompt reporting of test results; and

(iv) Ensure the adequacy and competency of the staff.

(D) As necessary, the laboratory shall revise policies and procedures based upon the results of those evaluations.

(2) All quality assurance/performance improvement activities shall be documented.

(3) The laboratory shall have an ongoing mechanism for monitoring and evaluating the following:

(A) The criteria established for:

(i) Patient preparation;

- (ii) Specimen collection;
- (iii) Labeling;
- (iv) Preservation; and
- (v) Transportation;

(B) The information solicited and obtained on the laboratory requisition for its:

- (i) Completeness;
- (ii) Relevance; and
- (iii) Necessity for testing patient specimens;

(C) The use and appropriateness of criteria established for specimen rejection;

(D) The completeness, usefulness, and accuracy of the test report information necessary for the interpretation or utilization of test results;

(E) The timely reporting of test results based on testing priorities (STAT, routine, manufacturer's instructions, etc.);

(F) The accuracy and reliability of:

- (i) Test reporting; and
- (ii) Record storage and retrieval;

(G) The effectiveness of corrective actions taken for:

(i) Problems identified during the evaluation of calibration and control data for each test method;

(ii) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and

(iii) Errors detected in previously reported test results; and

(H) The effectiveness of corrective actions taken for any unacceptable, unsatisfactory, or unsuccessful proficiency testing results.

(4) Laboratories that perform the same testing using different methodologies or instruments, or perform the same test at multiple testing sites, shall have a system that twice a year evaluates and defines the relationship between test results using different:

- (A) Methodologies;
- (B) Instruments; or
- (C) Test sites.

(5) Laboratories that perform tests that are not challenged with a proficiency testing program shall have a system for verifying the accuracy and reliability of their test results at least twice per year.

(6) The laboratory shall have a mechanism to identify and evaluate:

- (A) Patient test results that appear inconsistent with relevant criteria such as patient age, sex, diagnosis, or pertinent clinical data, when provided;
- (B) Distribution of patient test results, when available; and
- (C) Relationship with other test parameters, when available.

(7) The laboratory shall have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for ensuring employee competence.

(8)(A) The laboratory shall have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations.

(B) Corrective actions shall be taken, as necessary, to:

- (i) Resolve the problems; and
- (ii) Minimize communication breakdowns.

(9)(A) The laboratory shall have a system in place to ensure that all complaints and problems reported to the laboratory are documented.

(B) Investigations of complaints shall be made when appropriate and, as necessary, corrective actions shall be instituted.

(10)(A) The laboratory shall have a mechanism for:

- (i) Documenting and assessing problems identified during quality assurance/performance improvement reviews; and
- (ii) Discussing them with the staff.

(B) The laboratory shall take corrective actions that prevent reoccurrences.

(11)(A) The laboratory shall maintain documentation of all quality assurance/performance improvement activities, including problems identified and corrective actions taken.

(B) All quality assurance/performance improvement records shall be available and maintained for a period of two (2) years.

(o) **Safety.**

(1) The physical plant and environmental conditions of the laboratory shall provide a safe environment in which employees as well as all other individuals are protected from physical, chemical, and biological hazards.

(2) Safety precautions shall be established, posted, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards as well as biohazardous materials.

(p) **Point-of-care testing.**

(1) The requirements under this part apply only to the following tests that employ simple and accurate methodologies, as defined by the Centers for Disease Control and Prevention:

(A) Dipstick or tablet reagent urinalysis;

(B) Fecal occult blood;

(C) Urine pregnancy tests (visual color comparison);

(D) Hemoglobin by single analyte instrument with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout;

(E) Whole blood glucose by devices approved for home use;

(F) Spun microhematocrit;

(G) Whole blood immunoassay for *Helicobacter pylori*;

(H) Rapid test for Group A streptococcal antigen from throat swabs; and

(I) Glycosylated hemoglobin (Hgb Alc).

(2) All testing personnel shall have earned a high school diploma or equivalent.

(3) There shall be documentation that prior to testing patients' specimens each individual has:

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- (A) Received training for each test to be performed; and
- (B) Demonstrated the ability to perform all testing operations reliably.
- (4) Manufacturer's instructions for each of the tests shall be:
 - (A) Available in each area in which the specific test is performed; and
 - (B) Followed by all testing personnel.
- (5) Components of reagent kits of different lot numbers shall not be interchanged unless otherwise specified by the manufacturer.
- (6) Reagents, control and calibration materials, and other supplies shall be stored and handled in a manner to ensure that they are not used when:
 - (A) The expiration date has been exceeded; or
 - (B) They have deteriorated or are of substandard quality.
- (7)(A) Quality control procedures shall be performed in accordance with the manufacturer's instructions, at a minimum.
 - (B) Additional quality control procedures shall be performed as determined by the director of the hospital laboratory.
- (8) Maximum packing time of the microhematocrit centrifuge shall be determined at least every six (6) months.
- (9) The test record system shall include at least the following:
 - (A) Identification of the patient;
 - (B) Name of the authorized person who ordered the test;
 - (C) Test performed;
 - (D) Date and time of test performance;
 - (E) Identity of the person who performed the test;
 - (F) Test results; and
 - (G) Any additional information relevant and necessary for the interpretation of the results of a specific test.
- (10) The configuration of the test system shall be determined by the facility.
- (11) All required records shall be readily retrievable for at least two (2) years.
- (12) Point-of-care testing shall be included in the hospital laboratory's quality assurance/performance improvement program.

(13) Any tests other than those specified in subdivision (p)(1) of this section shall be subject to all of the requirements of this section.

20 CAR § 43-119. Radiological services.

(a) Radiology.

(1) Each hospital shall have shock-proof diagnostic X-ray facilities.

(2)(A) Radiological services shall be under the direction of a physician who is a member of the medical staff.

(B) The physician director shall be certified or eligible for examination by the American Board of Radiology.

(C)(i) At a minimum, a board-certified radiologist shall be available on a consultative basis.

(ii) Documentation of the radiologist's visits shall be required.

(3) Radiological services shall be supervised by a technologist who:

(A) Is qualified by experience or education; and

(B) Has at least two (2) years technical experience.

(4) A radiologic technologist with at least two (2) years training shall be:

(A) On duty twenty-four (24) hours; or

(B) On call at all times.

(5) Radiologic staff who use the radiologic equipment and administer procedures shall have:

(A) Written verification of training; and

(B) Approval in writing by the physician director.

(6) Radiologic technologists shall not independently perform fluoroscopic procedures.

(7)(A) Radiologic staff who administer agents for diagnostic purposes shall have written verification of training.

(B) A current list of radiology employees who administer agents for diagnostic purposes shall be:

(i) Approved by the physician director; and

(ii) Maintained by the facility.

(8) Radiology personnel who participate in direct patient care shall maintain competency in life support measures or the equivalent.

(9)(A) Clinically relevant educational programs shall be conducted at regularly scheduled intervals with not fewer than twelve (12) per year.

(B) There shall be evidence of:

- (i) Program dates;
- (ii) Attendance; and
- (iii) Subject matter.

(10)(A) Policies and procedures for the department shall have evidence of ongoing review and/or revision.

(B) The first page of each manual shall have the:

- (i) Annual review date; and
- (ii) Signature of the department and/or person or persons conducting

the review.

(C) Policies and procedures shall include:

- (i) Job descriptions for every type employee;
- (ii) A written list of all tests/procedures performed by the radiology department and the list shall be available to the medical staff;
- (iii) Infection prevention and control measures;
- (iv) The holding of patients;
- (v) Orientation practices for new employees;
- (vi) Operation of equipment;
- (vii) Management of an adverse reaction;
- (viii) Cleaning and disinfecting procedures; and
- (ix) Posting of signs.

(11) Radiology personnel shall receive yearly instruction in:

- (A) Safety precautions; and
- (B) Managing emergency radiation hazards and accidents.

(12) A documented preventive maintenance and quality control program shall include:

(A) Radiology personnel shall follow the dosimetry requirements identified in the Rules for Control of Sources of Ionizing Radiation, 20 CAR pt. 3;

(B)(i) Preventive maintenance for all diagnostic and therapeutic radiologic equipment to ensure a safe working condition.

(ii) Safety and calibration checks shall be made according to manufacturer's directions, not exceeding one (1) year intervals;

(C) Annual inspection of all leaded gloves, aprons, and similar protective devices at least once a year with documentation to include the:

(i) Name of the examiner;

(ii) Identification of the protective device examined; and

(iii) Results plus corrective action taken;

(D) Documentation of safety, calibration, and inspection checks maintained for the life of the equipment; and

(E) Remedial and corrective action recorded in response to equipment "down time", with documentation to include the:

(i) Piece of equipment involved;

(ii) Time/date malfunction occurred;

(iii) Action taken; and

(iv) Time/date when the equipment became operational.

(13) X-ray films shall not be stored in radiologic examination rooms.

(14) X-ray films shall be filed according to a recognized filing system.

(15) X-ray prescription/work requests shall:

(A) Be authorized by a written and signed physician's order; and

(B) Include the following:

(i) Identification of the patient;

(ii) Date the test was ordered;

(iii) Physician's name;

(iv) Concise statement as to the reason why the X-ray/test was ordered; and

(v) Originator's signature.

(16) The radiologic report shall be:

(A) Signed by a physician; and

(B) Placed in the medical record.

(17)(A) The radiological services shall have an ongoing QA/PI program that addresses patient care issues.

(B) A mechanism for reporting results of audits shall be provided, to include:

(i) Indicators monitored;

(ii) Thresholds/standards;

(iii) Results;

(iv) Corrective plan/corrective action taken; and

(v) Follow-up.

(18) This section establishes requirements for radiology that are in addition to, not in substitution of, the Rules for Control of Sources of Ionizing Radiation.

(19) Actual X-ray film shall be retained for five (5) years.

(20)(A) X-ray films and reports shall be stored in a room that is equipped with a smoke detection system.

(B) An extinguishing system shall be made available.

(21) Locked security shall be ensured for the written reports maintained in the X-ray file when the storage area is not under the direct supervision of radiology personnel.

(22) Dual image viewing shall be available in the OR, ER, and radiology areas.

(23) Facilities shall maintain the capacity to view X-ray films.

(b) Nuclear medicine services.

(1) Nuclear medicine procedures shall be under the direction of a physician, qualified in nuclear medicine, who is a member of the medical staff.

(2) Nuclear medicine services shall be supervised by a nuclear medicine technologist who has:

- (A) Completed certification requirements; and
- (B) At least two (2) years technical experience.

(3) Nuclear medicine staff who use the equipment and administer procedures shall have:

- (A) Written verification of training; and
- (B) Approval in writing by the physician director and medical staff.

(4) All radioactive materials shall be purchased, stored, administered, and disposed of in a manner consistent with the requirements of the:

- (A) Rules for Control of Sources of Ionizing Radiation; or
- (B) Specific condition of a radioactive material license issued pursuant to

this part.

(5)(A) The policy and procedure manual shall be reviewed annually and revised as necessary.

(B) Included in the manual shall be a cover page with:

- (i) Signatures of those reviewing the manual; and
- (ii) A month/day/year of review.

(C) The policies and procedures shall include:

- (i) Job description for each employee;
- (ii) A list of tests/procedures performed by nuclear medicine;
- (iii) Safety practices;
- (iv) Management of an adverse reaction;
- (v) Orientation for new employees;
- (vi) Operation of equipment;
- (vii) Cleaning and disinfecting procedures;
- (viii) Posting of signs;
- (ix) Quality control;
- (x) Quality assurance/performance improvement;
- (xi) Cleanup of spills;

- (xii) Receipt/disposal of radioactive materials; and
- (xiii) A radiation safety plan.

(6) All nuclear medicine personnel who participate in direct patient care shall maintain competency in life support measures.

(7)(A) There shall be a documented preventive maintenance and quality control program:

- (i) Monitoring of nuclear medicine personnel for exposure to radiation shall be integrated over a period not to exceed one (1) month;

- (ii) Nuclear medicine personnel shall follow the dosimetry requirements identified in the Rules for Control of Sources of Ionizing Radiation;

- (iii)(a) All nuclear medicine equipment shall be maintained in safe working condition.

- (b) Preventive maintenance, safety, and calibration checks shall be made according to manufacturer's directions, not to exceed one-year interval;

- (iv) Documentation of all safety, calibration, and inspection checks shall be maintained for the life of the equipment; and

- (v) Remedial and corrective action shall be recorded in response to equipment "down time".

(B) Documentation shall include the:

- (i) Piece of equipment involved;

- (ii) Time/date malfunction occurred;

- (iii) Action taken; and

- (iv) Time/date when equipment became operational again.

(8) The nuclear medicine "hot lab" shall be kept locked when not under the direct supervision of authorized personnel.

(9) There shall be an emergency eye wash available in the nuclear medicine "hot lab".

(10) All nuclear medicine staff who administer agents for diagnostic purposes shall have written verification of training and approval by the physician director and individual or individuals supervising the training.

(11)(A) Clinically relevant educational programs shall be conducted on regularly scheduled intervals at not fewer than twelve (12) per year.

(B) There shall be evidence of:

- (i) Program dates;
- (ii) Attendance; and
- (iii) Subject matter.

(12) All nuclear medicine requests shall:

(A) Be authorized by a written and signed physician's order; and

(B) Include the following:

- (i) Identification of the patient;
- (ii) Date;
- (iii) Physician's name;
- (iv) Originator's signature; and
- (v) Reason/justification for the test.

(13)(A) The nuclear medicine report shall be signed by a physician.

(B) The original shall be placed in the medical record.

(14) Films shall not be stored in radiologic or nuclear medicine examination rooms.

(15) The storage of nuclear medicine films shall comply with the guidelines under this section, radiological services.

(c) **Guidelines for mobile services.** The governing body and medical staff shall approve the provisions for establishing services in accordance with the following criteria:

(1) **General considerations.**

(A) The installation is governed by the following Department of Health publications:

- (i) This part; and
- (ii) Rules for Control of Source of Ionizing Radiation.

(B) Approvals shall be granted by the Department of Health:

- (i) Division of Health Facilities Services; and

(ii) State Radiation Control Agency and the Division of Emergency Management.

(C) The mobile service provider shall maintain fire, theft, general, and professional liability insurance;

(2) Operating policies.

(A) All examinations shall be authorized by a written and signed physician's order.

(B) Examinations shall be performed under the direction of and interpreted by a qualified physician with documented training or experience who is a member of the hospital's medical staff.

(C) Examinations shall be performed by a licensed radiologic technologist.

(D) The radiology department shall maintain current policies and procedures for use of the mobile units to include:

(i) Infection prevention; and

(ii) Control and safety.

(E) All personnel who administer agents for diagnostic purposes shall have written verification of training and approval by the physician director and individual or individuals supervising the training.

(F) Hospital personnel shall transport patients to and from the mobile unit according to hospital safety policies.

(G) Oxygen and emergency medical supplies shall be maintained and readily available.

(H) The hospital pharmacy may provide necessary medical supplies including contrast media, but proper handling and control of dated items shall be ensured.

(I) A log of all patients shall be maintained.

(J) Films shall be maintained in the same manner as X-ray films.

(K) Personnel who participate in direct patient care shall be competent in life support measures.

(L) Contracted services shall be under current agreement and the contractor shall fulfill all requirements of this section; and

(3) Refer to 20 CAR § 43-151, physical facilities — imaging suite.

20 CAR § 43-120. Physical therapy.

(a) "Licensed physical therapist" means any person licensed to practice physical therapy by the Arkansas State Board of Physical Therapy.

(b)(1) The practice of licensed physical therapy assistants shall be performed under the supervision of the licensed physical therapist.

(2) The supervising therapist shall be readily available for consultations, evaluations, and establishment of each program prior to:

(A) Delegation of any treatments; and

(B) Determination of patient discharge.

(c)(1) If physical therapy services are rendered by an individual who does not meet at least the assistant-level qualifications (aide/technician), a qualified physical therapist shall be on the premises and immediately available to provide assistance and direction throughout the time the services are rendered.

(2) Physical therapy services shall be provided under the direction of a physician member of the medical staff.

(3)(A) Physical therapy services shall be supervised by a physical therapist licensed by the board.

(B) Physical therapy assistants and aides shall comply with all state licensure requirements.

(4)(A) A policy and procedure manual for physical therapy shall be developed.

(B) The manual shall have evidence of ongoing review and/or revision.

(C) The first page of each manual shall have the:

(i) Annual review date; and

(ii) Signature of the department supervisor and/or person or persons conducting the review.

(5) There shall be written policies and procedures that shall include:

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- (A) Job descriptions for each type of employee;
 - (B) Infection prevention and control measures;
 - (C) Standards of care;
 - (D) Criteria for ensuring continuous communication of the patient's therapy and progress to the physician;
 - (E) Assembly and operation of equipment;
 - (F) Physical therapy services provided and a list of services made available to the medical staff;
 - (G)(i) Documentation specifying who may perform special procedures and give patient instruction.
 - (ii) This shall be verified by the physician director;
 - (H) Safety practices;
 - (I) Orientation practices for new employees; and
 - (J) Cleaning, disinfecting, and sterilizing procedures.
- (6) There shall be an adequate supply of reference material for the physical therapist that shall include current literature.
- (7) All physical therapy prescriptions/work requests shall be authorized by a written and signed physician's order.
- (8)(A) Equipment shall be:
- (i) Adequate for the services offered; and
 - (ii) Maintained in good repair.
- (B) Equipment shall be serviced, calibrated, and operated according to the manufacturer's directions.
- (C) All physical therapy equipment shall be under the control of the physical therapy supervisor.
- (D) A preventive maintenance program shall be implemented with:
- (i) Periodic inspection of all equipment; and
 - (ii) Appropriate records maintained for the life of each piece of equipment.

(E) All temperature-dependent patient use equipment shall have the temperature checked and recorded before each patient use or at least daily, if used, to ensure patient safety.

(9) Physical therapy records for each patient shall include:

- (A) Current written plan of care;
- (B) Statement of treatment objectives;
- (C) Statement of patient's short-term and long-term rehabilitation potential;
- (D) Functional limitations;
- (E) Justification of continued rehabilitative care; and
- (F) Documentation of daily treatments.

(10)(A) Clinically relevant educational programs shall be conducted on a regularly scheduled interval not fewer than twelve (12) times per year.

(B) There shall be evidence of:

- (i) Program dates;
- (ii) Attendance; and
- (iii) Subject matter.

(11) All physical therapy personnel who participate in direct patient care shall be competent in life support measures.

(12) There shall be an ongoing QA/PI program.

(13) Hospitals that have swimming pools shall comply with applicable sections of Rules Pertaining to Swimming Pools and Other Related Facilities, 20 CAR pt. 136.

(14) Contracted physical therapy services shall be under current agreement and the contractor shall fulfill all requirements of this section.

20 CAR § 43-121. Occupational therapy.

In facilities with an organized occupational therapy department, the following shall apply:

(1) Occupational therapy services shall be under the direction of a physician member of the medical staff;

(2) Occupational therapy services shall be supervised by a currently licensed therapist in the field of rehabilitation services;

(3) There shall be sufficient occupational therapy supportive technical staff to provide authorized occupational therapy services;

(4)(A) The policy and procedure manual shall have evidence of ongoing review and/or revision.

(B) The first page of each manual shall have the:

(i) Annual review date; and

(ii) Signature of the department supervisor and/or person or persons conducting the review;

(5) There shall be written policies and procedures that shall include:

(A) Job descriptions for every type of employee;

(B)(i) Documentation specifying who may:

(a) Perform special procedures; and

(b) Give patient instructions;

(ii) This shall be verified by the physician director;

(C) Orientation practices for new employees;

(D) Occupational therapy services provided and a list of services provided to the medical staff; and

(E) Safety practices;

(6) Current reference material shall be available for the occupational therapist;

(7) All occupational therapy prescriptions/work requests shall be authorized by a written and signed physician's order;

(8)(A) Equipment shall be adequate for the services offered and maintained in good repair.

(B) Equipment shall be serviced, calibrated, and operated according to the manufacturer's directions.

(C) All occupational therapy equipment shall be under the control of the occupational therapy supervisor.

(D) A preventive maintenance program shall be implemented with:

- (i) Periodic inspection of all equipment; and
- (ii) Appropriate records maintained for the life of each piece of equipment.

(E)(i) All temperature-dependent patient use equipment shall have the temperature checked and recorded before each patient use.

(ii) When appropriate elements are planned and arranged for shared use by physical therapy patients and staff, one (1) or both services shall be responsible for the:

- (a) Preventive maintenance program; and

- (b) Retention of records;

(9) Occupational therapy records for each patient shall include:

- (A) Current written plan of care;

- (B) Statement of treatment objectives;

- (C) Statement of patient's short-term and long-term rehabilitation potential;

- (D) Justification of any continued rehabilitation care; and

- (E) Documentation of the patient's condition and response to treatments;

(10)(A) Clinically relevant educational programs shall be conducted on a regularly scheduled basis at not fewer than twelve (12) per year.

(B) There shall be evidence of:

- (i) Program dates;

- (ii) Attendance; and

- (iii) Subject matter;

(11) All occupational therapy personnel shall maintain competency in life support measures;

(12) There shall be an ongoing QA/PI program; and

(13) Contracted occupational therapy services shall be under current agreement and the contractor shall fulfill all requirements of this section.

20 CAR § 43-122. Speech pathology/audiology services.

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In facilities with an organized speech language pathology/audiology services department, the following shall apply:

(1) Speech pathology/audiology services shall be under the direction of a physician member of the medical staff;

(2) Speech pathology/audiology services shall be supervised by a therapist who is currently licensed;

(3) There shall be sufficient supportive personnel to provide authorized speech pathology/audiology services;

(4) There shall be documentation, verified by the physician director, of who may:

(A) Perform special procedures; and

(B) Give patient instructions;

(5)(A) Policies and procedures shall have evidence of ongoing review and/or revision.

(B) The first page of each manual shall have the:

(i) Annual review date; and

(ii) Signature of the department supervisor and/or person or persons conducting the review;

(6) There shall be written policies and procedures that shall include:

(A) Job descriptions for every type of employee;

(B) Orientation procedures for new employees;

(C) Infection prevention and control measures;

(D) A listing of services/treatments available to the medical staff; and

(E) Safety practices;

(7)(A) Equipment shall be in good repair and under the control of the therapist supervisor.

(B) Documentation of preventive maintenance shall be maintained for the life of each piece of equipment;

(8) Current reference material shall be available for the department;

(9)(A) Clinically relevant educational programs shall be conducted on a regularly scheduled basis at not fewer than twelve (12) per year.

(B) There shall be evidence of:

- (i) Program dates;
- (ii) Attendance; and
- (iii) Subject matter;

(10) All speech pathology/audiology prescriptions/work requests shall be authorized by a written and signed physician's order;

(11) Speech pathology/audiology services records for each patient shall include:

- (A) Current written plan of care;
- (B) Statement of treatment objectives;
- (C) Statement of patient's short-term and long-term rehabilitation potential;
- (D) Justification of any continued rehabilitation care; and
- (E) Documentation of progress notes following treatment given to patients;

(12) All speech pathology/audiology personnel shall maintain competency in life support measures;

(13) There shall be an ongoing QA/PI program; and

(14) Contracted speech pathology/audiology services shall be under current agreement and the contractor shall fulfill all requirements of this section.

20 CAR § 43-123. Recreational therapy.

In facilities with organized recreational therapy services, the following shall apply:

(1) Recreational therapy services shall be under the direction of a physician member of the medical staff;

(2) Recreational therapy services shall be supervised by a therapist with current certification;

(3) There shall be sufficient recreational therapy supportive staff to provide authorized recreational therapy services;

(4) There shall be documentation, verified by the physician director, of who may:

(A) Perform special procedures; and

(B) Give patient instructions;

(5)(A) The policy and procedure manual shall have evidence of ongoing review and/or revision.

(B) The first page of the manual shall have the:

(i) Annual review date; and

(ii) Signature of the department supervisor and/or person or persons conducting the review;

(6) There shall be written policies and procedures that shall include:

(A) Job descriptions;

(B) Infection prevention and control measures;

(C) Recreational therapy services provided and a list of services shall be made available to the medical staff;

(D) Orientation practices for new employees and volunteer personnel;

(E) Assembly, operation, and maintenance of all equipment;

(F) Safety practices;

(G) Security of supplies and tools; and

(H) Activities off campus;

(7)(A) All equipment, tools, and machines shall be:

(i) In good repair; and

(ii) Under the control of the therapist supervisor.

(B) Documentation of preventive maintenance shall be maintained for the life of each piece of equipment;

(8) Current reference material shall be available for the department;

(9)(A) Clinically relevant educational programs shall be conducted on a regularly scheduled basis at not fewer than twelve (12) per year.

(B) There shall be evidence of:

- (i) Program dates;
- (ii) Attendance; and
- (iii) Subject matter;

(10) All recreational therapy prescriptions/work requests shall be authorized by a written and signed physician's order and shall include:

- (A) Identification of the patient;
- (B) Date;
- (C) Physician's name;
- (D) Type, frequency, and duration of treatment; and
- (E) Originating signature;

(11) Recreational therapy service records for each patient shall include:

- (A) Current written plan of care;
- (B) Documentation of:
 - (i) Attendance by the therapist in team meetings; and
 - (ii) The contribution by the therapist to the treatment plan;
- (C) Statement of treatment objectives;
- (D) Statement of patient's short-term and long-term rehabilitation potential;
- (E) Record of daily activity participation;
- (F) Justification of any continued rehabilitation care; and
- (G) Progress notes;

(12) All recreational therapy personnel shall maintain competency in life support measures;

(13) There shall be an ongoing QA/PI program;

(14) If food and/or nutritional service functions are offered, infection prevention and control, storage and supervision shall be coordinated with the dietary department of the facility; and

(15) Contracted recreational therapy services shall be under current agreement and the contractor shall fulfill all requirements of this section.

20 CAR § 43-124. Pet therapy program.

(a) **Definitions.** As used in this section:

(1) "Handler" means an individual who has been specifically credentialed and authorized by the hospital to participate in, and to accompany and control pets participating in, the program;

(2) "Pet" means an animal that has been specifically screened, trained, and authorized by the hospital to participate in the program; and

(3) "Program" means the pet therapy program.

(b) The program shall be approved by the:

(1) Governing body;

(2) Medical staff; and

(3) Infection Prevention and Control Committee.

(c) The Infection Prevention and Control Committee shall, in conjunction with a licensed veterinarian, establish the medical criteria that each pet shall meet in order to participate in the program.

(d) The hospital shall establish the behavioral criteria that each pet shall meet before participating in the program.

(e) A licensed veterinarian shall certify that a participating pet:

(1) Meets the hospital's medical criteria; and

(2) Is free of zoonotic communicable disease-causing organisms.

(f) A licensed veterinarian, a local protection society, or a pet therapy association or society shall certify that a participating pet meets the hospital's behavioral criteria.

(g)(1) Pets found to have a communicable disease shall be excluded from the pet therapy program until the pet is treated and has one (1) negative culture, if culturing of the causative agent is feasible.

(2) Pets expressing behavioral problems will be excluded from the program until the behavioral problem is remedied.

(h)(1) Pets shall be bathed and groomed before each hospital visit.

(2) Pets shall be free of fleas while visiting the hospital.

- (i)(1) The hospital shall establish an orientation program for the handlers.
- (2) Handlers shall attend this program before participating in the program.
- (3) The orientation program shall include, at least:
 - (A) Patient confidentiality;
 - (B) Appropriate infection prevention and control measures;
 - (C) Safety; and
 - (D) Appropriate emergency protocols.
- (4) Records of the orientation program shall be kept.

(j)(1) The hospital shall keep records of each visit the pet makes.

- (2) The records shall include, at least:
 - (A) The date;
 - (B) The identity of the pet;
 - (C) The identity of the handler;
 - (D) All the patients visited;
 - (E) The area in which the patient visits were made; and
 - (F) Any infectious condition the patient had or any type of isolation the

patient was in at the time of the visit.

(k)(1) The pet and handler shall be escorted at all times by a staff member appropriate to the area visited.

- (2) Patient safety and confidentiality shall be maintained at all times.

(l)(1) The pet shall be:

- (A) Under the direct supervision of the handler at all times; and
- (B) On a leash or in a crate at all times while in the hospital.

(2) Other patients, visitors, and employees shall be discouraged from petting the pet.

(m)(1) The hospital shall provide an area to walk the pet.

- (2) There shall be procedures for immediate cleanup of all accidents.

(n)(1) There shall be procedures for:

- (A) Patient handwashing;
- (B) Visit area cleanup; and

(C) Cleaning of the patient's room.

(2) If a pet visits a patient in bed, the bed linens will be changed immediately after the visit.

(3) A barrier shall be placed over the bed if the pet is placed directly on the patient's bed.

(o)(1) The attending physician in conjunction with the infection control officer will determine the appropriateness of the pet visits.

(2) The attending physician shall approve and order each pet visit.

(3) The orders shall be documented in the medical record.

20 CAR § 43-125. Specialized services — Surgical services.

(a) Organization and supervision.

(1) An organizational plan shall be developed.

(2) Surgical services shall be under the medical direction of a qualified physician or a physician committee.

(3) A surgical services registered nurse supervisor shall be accountable and responsible for patient care.

(4)(A) Surgical services shall have written policies and procedures that include:

(i) Operative and special consents;

(ii) Fire and disaster plans;

(iii) Environmental control;

(iv) Visitor and traffic control to include allowance for no one other than staff or professionals without the expressed consent of the physician and operating room supervisor;

(v) Safety practices;

(vi) Infection prevention and control measures;

(vii) Care and disposition of:

(a) Surgical specimens;

(b) Cultures; and

(c) Foreign bodies;

(viii) Care of special equipment including preventive maintenance contracts and records;

(ix) Emergency management;

(x) Orientation of all personnel; and

(xi) Medication accountability.

(B) Refer to:

(i) 20 CAR § 43-110, patient care service; and

(ii) 20 CAR § 43-115, pharmacy.

(5)(A) Clinically relevant educational programs shall be conducted on a regularly scheduled basis not fewer than twelve (12) per year.

(B) There shall be evidence of:

(i) Program dates;

(ii) Attendance; and

(iii) Subject matter.

(6) A surgery schedule shall be maintained in the surgery suite.

(7) There shall be a continuous QA/PI program that is specific to the patient care administered.

(8) A current roster of physicians and dentists with a delineation of each physician's and dentist's surgical privileges shall be accessible and available in the:

(A) Confidential files of the surgical services registered nurse; and

(B) Files of the hospital administrator.

(9) The following information shall be maintained in the surgery services log:

(A) Patient's full name;

(B) Hospital number;

(C) Surgeon;

(D) Assistant surgeon;

(E) Type of anesthetic and person administering;

(F) Preoperative and postoperative diagnoses;

(G) Circulating nurse;

(H) Scrub nurse or nurses;

- (I) Procedures;
- (J) Complications;
- (K) Sponge, needle, and instrument count;
- (L) Time of beginning and ending of case; and
- (M) Other persons present.

(b) Environment, equipment, and supplies.

(1) A safe operating room environment shall be:

- (A) Established;
- (B) Controlled; and
- (C) Consistently monitored.

(2) At a minimum, the following general equipment and supplies shall be in the surgical suite:

- (A) Call-in system;
- (B) Crash cart;
- (C) Cardiac monitor;
- (D) Defibrillator;
- (E) Resuscitating equipment;
- (F) Suction equipment; and
- (G) Thoracotomy set.

(3) Equipment and supplies necessary to meet the requirements of the services provided:

- (A) Stretcher;
- (B) Anesthetic equipment and supplies;
- (C) Adjustable operating table with waterproof pad;
- (D) Side tables;
- (E) Approved surgical light;
- (F) Medical gases;
- (G) Twenty-four-hour supply of sterile linen;
- (H) Wall clock; and
- (I) Equipment and supplies for timed scrubbing technique.

(c) **Staffing.**

(1) Surgical personnel including a registered nurse shall be available to provide emergency surgical services on a twenty-four-hour basis.

(2)(A) A registered nurse shall be present in the operating room for the duration of the surgical procedure.

(B) Additional auxiliary personnel shall be available as necessary.

(3) Only qualified registered nurses may perform circulating duties in the operating room.

(4) There shall be documentation of training and/or experience for all operating room personnel assigned to surgical procedures.

20 CAR § 43-126. Specialized services — Postanesthesia care unit.

(a) Postanesthesia care unit (PACU) services shall be provided in a well-organized manner under the:

(1) Direction of a qualified physician; and

(2) Supervision of a registered nurse.

(b)(1) Policies and procedures shall have evidence of ongoing review and/or revision.

(2) The first page of each manual shall have the:

(A) Annual review date; and

(B) Signature of the department supervisor and/or person or persons conducting the review.

(3) Policies and procedures shall include:

(A) Lines of authority and nursing supervision;

(B) Transfer of patients from the operating room to the postanesthesia care unit;

(C) Criteria for discharge of patients from the postanesthesia care unit; and

(D) The care of patients in the event the postanesthesia care unit closes, including provisions of adequate nursing staff.

(c) There shall be adequate nursing staff in attendance with every patient during anesthesia recovery.

(d) A physician shall order the discharge of the patient from the postanesthesia care unit.

(e) Equipment shall be available in accordance with services provided.

(f) The registered nurse shall assess and document assessment of each PACU patient.

(g)(1) Clinically relevant educational programs shall be conducted on a regularly scheduled basis of not fewer than twelve (12) per year.

(2) There shall be evidence of:

(A) Program dates;

(B) Attendance; and

(C) Subject matter.

(h) There shall be an ongoing QA/PI program that is specific to the patient care administered.

20 CAR § 43-127. Specialized services — Ambulatory surgery services.

(a)(1) There shall be policies and procedures specific to ambulatory surgery services.

(2) Policies and procedures for the department shall have evidence of ongoing review and/or revision.

(3) The first page of each manual shall have the:

(A) Annual review date; and

(B) Signature of the department supervisor and/or person or persons conducting the review.

(b)(1) Policies and procedures shall include:

(A) Scheduling of patients for surgery;

(B) Admission and discharge criteria;

(C) Perioperative patient care;

(D) Operative and special consents;

(E) Obtaining a documented history and physical on the patient's medical record prior to the procedure;

(F) Preoperative assessment procedures required by the medical staff;
and

(G) Medication accountability.

(2) Refer to:

(A) 20 CAR § 43-110, patient care service;

(B) 20 CAR § 43-111, medications; and

(C) 20 CAR § 43-115, pharmacy.

(c) A physician shall order the discharge of the patient from the facility.

(d) For additional requirements, refer to:

(1) Patient care service, 20 CAR § 43-110;

(2) Specialized services — surgical services, 20 CAR § 43-125; and

(3) Specialized services — postanesthesia care unit, 20 CAR § 43-126.

20 CAR § 43-128. Specialized services — Anesthesia services.

(a) Organization and staffing.

(1) Anesthesia services shall be provided in a well-organized manner under the direction of a qualified physician.

(2) The service is responsible for all anesthesia administered.

(b)(1) Those administering anesthesia shall be:

(A) Credentialed by medical staff; and

(B) Approved by the governing body.

(2) A current roster with delineation of privileges for those administering anesthesia shall be maintained and readily available.

(c) Anesthesia shall be administered by the following:

(1) Anesthesiologist;

(2) Physician qualified to administer anesthesia; or

(3) Certified registered nurse anesthetist (CRNA) in consultation with a physician.

(d)(1) Written policies and procedures specific to anesthesia services shall have evidence of ongoing review and/or revision.

(2) The first page of the manual shall have the:

(A) Annual review date; and

(B) Signature of the department supervisor and/or person or persons conducting the review.

(e) Policies and procedures shall include:

(1) Preanesthesia evaluation;

(2) Approved anesthesia agents;

(3) Methods of delivery of anesthesia;

(4) Intraoperative anesthesia record;

(5) Postanesthesia follow-up report;

(6) Mechanism for routine checking and maintenance of anesthesia machines and equipment for safe use;

(7)(A) Medication accountability.

(B) See:

(i) 20 CAR § 43-110, patient care service;

(ii) 20 CAR § 43-111, medications; and

(iii) 20 CAR § 43-115, pharmacy;

(8)(A) Responsibilities in the discharge of patients from the postanesthesia care unit.

(B) See 20 CAR § 43-126, specialized services — postanesthesia care unit; and

(9) Infection prevention and control measures.

(f)(1) All medications and anesthetic agents administered to the patient shall be ordered by the prescriber and/or anesthesia provider.

(2) This includes preoperative as well as intraoperative and postoperative medications.

(g) There shall be an ongoing QA/PI program that is specific to the patient care administered.

20 CAR § 43-129. Specialized services — Labor, delivery, labor delivery recovery (LDR), labor delivery recovery postpartum (LDRP), postpartum, and maternal-child education.

(a) Labor room and/or LDR, LDRP room.

(1)(A) Provisions shall be made for patients in labor in either a:

- (i) Designated labor room; and/or
- (ii) Birthing room.

(B) Rooms used only for labor shall be in close proximity to the delivery room.

(C) Furniture, washable wallpaper, pictures, radio, television, and other items may be used as long as the needs of the mother and baby are not compromised.

(D) Items selected shall be made of durable materials with a smooth, impervious surface that can be easily cleaned and disinfected.

(2) All beds used for labor shall be equipped with side rails.

(3) There shall be equipment and supplies available for the examination and preparation of patients in labor that shall consist of the following:

- (A) Precipitous delivery tray;
- (B) Stethoscope;
- (C) Suction equipment;
- (D) Sterile gloves;
- (E) Emergency medications as approved by the Pharmacy and

Therapeutics Committee and supplies to include:

- (i) Laryngoscopes;
- (ii) Airways;
- (iii) Endotracheal tubes; and
- (iv) Infant Ambu bags; and
- (F) Fetal monitoring device.

(4)(A) A physician shall be immediately available when oxytocin is administered.

(B) "Immediately available" shall be determined by the hospital's:

- (i) Administrative staff;
- (ii) Medical staff; and
- (iii) Governing body.

(5) Father or support persons may be allowed with the patient during labor unless medically contraindicated.

(b) Delivery areas.

(1)(A) Hospitals offering delivery and maternity services shall comply with the requirements of this section.

(B) See:

- (i) 20 CAR § 43-110, patient care service; and
- (ii) 20 CAR § 43-113, Health Information Services.

(2)(A) General operating rooms may not be used for deliveries, except for major surgical deliveries.

(B) Delivery rooms shall:

- (i) Be separate from operating rooms; and
- (ii) Not be used for any other purpose, with the exception of a tubal ligation immediately following a delivery.

(C) Delivery rooms may be used for Caesarean sections provided:

- (i) The usual operating room equipment is used; and
- (ii) Surgical policies and procedures related to the delivery are made a part of the labor and delivery manual.

(3) The following equipment and supplies shall be provided:

(A) Supply of medications as approved by the Pharmacy and Therapeutics Committee;

(B)(i) Infant identification and supplies.

(ii) Identification shall be done in the delivery room at the time of birth and shall remain in place during the entire period of hospitalization.

(iii) Identification information shall be sufficient to identify the infant or infants with one (1) mother.

(iv) Identification bands shall be waterproof plastic with tag inserts written in waterproof ink;

(C) Heated bassinet, crib, or incubator;

(D)(i) Supply of prophylaxis medication for the prevention of infant blindness.

(ii) The medication shall be administered within one and one-half (1 1/2) hours of the time of birth per written order of the physician;

(E) Commercially manufactured delivery table/birthing bed with a waterproof nonconductive table pad;

(F) Side tables for instruments and other necessary equipment;

(G) Approved surgical light;

(H) Wall clock;

(I) Equipment and supplies for timed scrub technique and an approved disinfectant soap;

(J) Apgar score chart;

(K) Suction equipment, infant and adult;

(L) Sphygmomanometer; and

(M) Fetal monitoring device.

(c) Organization.

(1)(A) Delivery services shall be under the:

(i) Direction of a qualified physician; and

(ii) Supervision of a registered nurse.

(B) A registered nurse shall be present during labor, delivery, and postdelivery of each patient.

(C) The birth shall be attended by a physician or a certified nurse midwife with hospital privileges.

(2)(A) Patients shall be provided with direct care by a registered nurse during:

(i) Labor;

(ii) Delivery;

(iii) Recovery; and

(iv) Postpartum.

(B) All patients in active labor shall be attended and/or monitored.

(C) Qualified nurses in adequate numbers shall be provided to meet the needs of each patient.

(3)(A) An on-call schedule shall be provided to ensure that a physician with obstetrical privileges is readily available to perform obstetrical services at all times.

(B) "Readily available" shall be determined by the hospital's:

(i) Administrative staff;

(ii) Medical staff; and

(iii) Governing body.

(4)(A) Qualified registered nurses shall always be available in-house for labor and delivery patients.

(B) When there are no patients, on-call staff may be utilized if approved by the medical staff and governing body.

(5) Procedures for obtaining the mother's Rh factor shall be provided by the facility or documented by the mother's attending physician upon admission.

(6) When a patient presents to the hospital for evaluation, the physician or certified nurse midwife shall be notified.

(7) Policies and procedures shall include:

(A) Immediate delivery;

(B) Obstetrical emergencies;

(C) Setting up and cleaning the:

(i) Delivery room;

(ii) LDR or LDRP room; and

(iii) C-section room;

(D) Equipment requirements;

(E) Visitation;

(F) Climate control (physical);

(G) Infection prevention and control measures;

(H) Aseptic techniques;

- (I) Intermittent rooming in;
- (J) Anesthesia;
- (K) Deliveries occurring outside the delivery area;
- (L) Infectious patients; and
- (M) Infant security.

(8)(A) A permanent record of all deliveries shall be maintained.

(B) There shall be a reasonable attempt to collect current information to include the following:

(i) Mother's:

- (a)* Name;
- (b)* Date of birth;
- (c)* Maiden name;
- (d)* Father's name if available;
- (e)* Hospital number;
- (f)* Gravida-para;
- (g)* ABO type;
- (h)* Rh factor;
- (i)* Mother's Hepatitis C status; and
- (j)* Length of gestational period;

(ii) Baby's:

- (a)* Sex;
- (b)* Race;
- (c)* Date of birth;
- (d)* Time of birth;
- (e)* Weight;
- (f)* Apgar score; and
- (g)* Baby identification band number.

(C) The healthcare provider shall record in the medical record if the pregnant woman declines to be tested for Hepatitis C.

(d) **Anesthesia.**

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(1) Only a physician, anesthesiologist, or certified registered nurse anesthetist (CRNA) shall be permitted to:

- (A) Initiate and reinject continual epidural or caudal anesthesia; and
- (B) Initiate or continue general or regional anesthesia.

(2)(A) A physician shall be immediately available for consultation if CRNAs are administering anesthesia.

(B) "Immediately available" shall be determined by the hospital's:

- (i) Administrative staff;
- (ii) Medical staff; and
- (iii) Governing body.

(3) The permanent record shall contain the names of the:

- (A) Physician;
- (B) Anesthesiologist;
- (C) Anesthetist; or
- (D) CRNA.

(e) Postpartum care.

(1) Policies and procedures shall be developed specific to the care of maternity patients.

(2) Maternity patients shall not be routinely cared for in rooms with patients admitted for diagnosis other than maternity.

(3) After an observation period, the infant may stay in the room with the mother for the duration of the hospital stay.

(4) Mothers with infection, fever, or other condition that could adversely affect the safety and welfare of others shall be immediately:

- (A) Segregated; and
- (B) Isolated in a separate room.

(f) Maternal-child education.

(1) The hospital shall develop an educational program for the care of the obstetrical patient and infant.

(2) Policies and procedures shall include:

- (A) Personal hygiene;
- (B) Dietary instruction;
- (C) Care of episiotomy and perineum;
- (D) Care of incision;
- (E) Breast care;
- (F) Exercise program;
- (G) Car seat safety, the Child Passenger Protection Act, Arkansas Code § 27-34-101 et seq.;
- (H) Preventive health;
- (I) Referral services;
- (J) Infant care;
- (K) Hepatitis C counseling; and
- (L) Distributing educational materials for shaken baby syndrome, Arkansas Code § 20-9-1401 et seq.

20 CAR § 43-130. Nursery services.

- (a) The newborn nursery shall be under the direct supervision of a registered nurse with clinical skills in newborn nursing.
- (b) The newborn nursery shall be located within or adjacent to the postpartum unit.
- (c) The following requirements shall apply to all nurseries:
 - (1) Nurseries shall:
 - (A) Not be used for any other purpose; and
 - (B) Never be left unattended when occupied;
 - (2)(A) Infants born outside the hospital or with proven or potential infections shall be isolated from other infants in the nursery.
 - (B) Infants with infections, skin rash, or diarrhea shall be immediately separated and isolated;
 - (3)(A) Isolettes shall not serve as a sole means of isolation.
 - (B) Provisions for isolation shall be provided;

- (4) The following equipment shall be provided in nurseries:
- (A)(i) Individual approved-type hospital bassinets.
 - (ii) Wicker-type or woven-type bassinets shall not be used;
 - (B)(i) Metal or approved plastic diaper and waste containers.
 - (ii) The lids on these containers shall be operated by a foot control or equivalent device;
 - (C) Infant scales;
 - (D) Blankets and linen;
 - (E) Suction equipment; and
 - (F) Incubators suitable for the care of premature infants provided in the ratio of at least one (1) incubator to twenty (20) bassinets;
- (5) Infant emergency supplies:
- (A) Emergency medications approved by the Pharmacy and Therapeutics Committee;
 - (B) Infant laryngoscope;
 - (C) Suction catheters;
 - (D) Endotracheal tubes;
 - (E) Stylets; and
 - (F) Infant airways and IV supplies;
- (6)(A) Newborn testing for critical congenital heart defects shall include the performance of pulse oximetry testing all newborns before discharge.
- (B) See Arkansas Code § 20-9-103.
 - (C) Performance of a pulse oximetry test on a newborn is not required if the parent or legal guardian of the newborn objects to the testing on medical, religious, or philosophical grounds;
- (7) Newborn testing for genetic illnesses shall be in accordance with:
- (A) Rules Pertaining to Testing of Newborn Infants, 20 CAR pt. 107; and
 - (B) Arkansas Code § 20-15-302;
- (8) Newborn testing for early detection of hearing loss shall be in accordance with:

(A) Rules for Universal Newborn Hearing Screening, Tracking, and Intervention Program and Advisory Board, 20 CAR pt. 11; and

(B) Arkansas Code § 20-15-1105;

(9)(A) Strict hand hygiene techniques shall be maintained by all personnel.

(B) A clean barrier shall be used by anyone handling the infant;

(10)(A) Infant clothing shall be furnished by the hospital.

(B) However, if the mother wishes to provide clothing for the infant, hospital personnel shall examine the clothing to make sure it meets hospital requirements.

(C) Diapers shall be available in necessary quantities;

(11) **Formula feedings.**

(A) Any individually packaged, presterilized formula delivered by an outside source shall be approved by the facility.

(B) There shall be an adequate supply of sterile disposable ready-to-use formula bottles available.

(C) Formulas shall be stored in enclosed cabinets.

(D) The expiration date shall be checked on each bottle prior to infant feeding.

(E) Policies and procedures shall be developed in conjunction with the Infection Prevention and Control Committee regarding the handling, labeling, and storing separately of breastmilk.

(F) Individual nipple shields and breast pumps used in infant feeding shall be cleaned according to hospital infection prevention and control policies and procedures.

(G) If the facility has a breastmilk bank, the policies and procedures shall be submitted to and approved by the:

(i) Department of Health; and

(ii) Hospital Infection Prevention and Control Committee; and

(12) **Rooming-in service.** Hospitals providing a newborn nursery may provide rooming in for infants on an intermittent or twenty-four-hour basis based on the mother's request.

20 CAR § 43-131. Specialized services — Critical care.

(a) A critical care unit is a section of the hospital where intensive care nursing, necessary monitoring and treatment equipment, and supplies are provided to those patients who, in the opinion of the attending physician, require such specialized services.

(b) **Staffing.**

(1) Critical care units shall be staffed with a registered nurse each shift.

(2)(A) All critical care nursing staff shall:

(i) Be oriented and trained in life support measures and interpretation of dysrhythmias; and

(ii) Demonstrate competency in critical care nursing specific to patient types.

(B) Competency in the specific areas shall be maintained.

(c) **Policies and procedures.** Procedures shall include:

(1) Admission and continuing stay criteria;

(2) Discharge criteria;

(3) Triage/transfer;

(4) Use of protocols; and

(5) Definition of the clinical scope of the hospital's critical care service.

(d) **Equipment.** Equipment shall include:

(1) Suction;

(2) Diagnostic monitoring equipment to include electrocardiographic monitoring;

(3) Crash cart containing emergency medications and supplies;

(4) Defibrillator;

(5) Wall clock;

(6) Accommodations to maintain privacy; and

(7) Weighing device for bed patients.

(e) **Isolation.** An isolation room shall be available for the treatment of potentially infectious or immune-suppressed critical care patients.

(f) **Pediatric critical care.** If the facility offers critical care for the pediatric patient there shall be:

(1) Policies, procedures, and equipment specific to the needs of pediatric patients; and

(2) Nursing staff oriented and trained in life support measures, interpretation of dysrhythmias, and competency in critical care nursing specific to the pediatric patient.

20 CAR § 43-132. Specialized services — Dental services.

(a)(1) Dental services shall comply with the requirements of this section.

(2) See:

(A) 20 CAR § 43-110, patient care service;

(B) 20 CAR § 43-113, Health Information Services;

(C) 20 CAR § 43-115, pharmacy; and

(D) All applicable sections.

(b)(1) Patients admitted to the hospital for dental care shall be given the same medical appraisal as those admitted to other services.

(2) The care of dental patients shall be the dual responsibility of the dentist and a physician on the hospital staff.

(c) Dental services shall be under the direction of a dentist.

(d) Policies and procedures shall be provided.

20 CAR § 43-133. Specialized services — Central sterilization and supply.

(a)(1) Each hospital shall provide central medical and surgical supply services with facilities that are responsible for processing, sterilizing, storing, and distributing supplies and equipment to all units of the hospital.

(2) Refer to 20 CAR § 43-161, physical facilities — central medical and surgical supply department, for space and equipment requirements.

(b) The central sterilization and supply service shall be under the direct supervision of a registered nurse or other qualified person who is trained in management, aseptic procedures, supply processing, and control methods that are applicable to central sterilization and supply service.

(c)(1) Policies and procedures shall have evidence of ongoing review and/or revision.

(2) The first page of each manual shall have the:

(A) Annual review date; and

(B) Signature of the department and/or person or persons conducting the review.

(d) Policies and procedures shall include:

(1) Job descriptions;

(2) Infection prevention and control measures;

(3) Assembly and operation of equipment;

(4) Safety practices;

(5) Orientation for new employees;

(6) Care and cleaning of equipment;

(7) Evaluation of:

(A) Cleaning effectiveness; and

(B) Sterilizing effectiveness;

(8) Receiving, decontaminating, cleaning, preparing, disinfecting, and sterilizing reusable items;

(9) Assembling and wrapping of packs to include the double-wrapped techniques;

(10) Storage and distribution of sterile equipment/medical supplies;

(11) Use of chemical indicators and biological spore tests for sterilizers;

(12) Recalling and disposing/reprocessing of outdated sterile supplies;

(13) Cleaning and disinfecting of surfaces, utensils, and equipment;

- (14) Specifications for cold-liquid sterilization and gas sterilization, if used; and
- (15) Collection and disposal of supplies recalled by the manufacturer.
- (e) There shall be an ongoing QA/PI program specific to the area.
- (f)(1) Precautions shall be exercised to prevent the mixing of sterile and unsterile supplies and equipment.
 - (2) The precautions shall be set forth in written policies.
- (g)(1) Procedures shall be developed for unloading and transporting flash-sterilized items.
 - (2) The procedures shall:
 - (A) Be developed with the assistance of the Infection Prevention and Control Committee; and
 - (B) Provide for the aseptic transfer within the physical constraints of the facility.
 - (h)(1) Relevant educational programs shall be conducted on a regularly scheduled basis of not fewer than twelve (12) per year.
 - (2) There shall be written documentation with:
 - (A) Employee signature;
 - (B) Program title/subject;
 - (C) Presenter;
 - (D) Date; and
 - (E) Outline or narrative of presented program.
 - (i) A liaison with the Infection Prevention and Control Committee shall be maintained.
 - (j)(1) Records shall be maintained of all autoclave loads, both routine and immediate use or "flash" that shall:
 - (A) Include the date, time, lot number on routine loads, the time at temperature where a recorder is not available, item or items sterilized; and
 - (B) Identify the person performing the task.
 - (2) Autoclaves shall meet the following requirements:

(A) The efficacy of autoclaves, both for routine and immediate use or “flash” use, shall be determined weekly through the use of biological spore monitors;

(B) The results of all biological spore monitoring shall be reported to the Infection Prevention and Control Committee; and

(C) Failures of the biological spore test shall be brought to the attention of the Infection Prevention and Control Officer or designee immediately so the appropriate surveillance measures can be initiated.

(3) **Note.** All materials sterilized from the date of the biological spore monitor failure to the last successful biological spore monitor shall be resterilized before use.

(k)(1) All autoclaves within the facility shall be maintained in accordance with the manufacturer’s written directions.

(2) Records shall be maintained of all maintenance and repairs for the life of the equipment.

(l) Chemical indicators for sterility shall be used with each cycle.

(m)(1) The facility shall validate compliance and efficacy of the sterilization policy through the quality review process.

(2) The sterilization policy shall describe the mechanism used to determine the shelf life of sterilized packages.

(3) The policy shall:

(A) Be consistent with published industry standards (AAMI and APIC); and

(B) Stress that sterility is related to integrity of pack regardless of whether expiration dating or event-related expiration is utilized.

(n)(1) Event-related dating of sterile packs is acceptable.

ALLOWABLE SHELF LIFE

Double-wrapped Muslin

Use for rapid turn-around items only in well controlled environment, < 30 days

Double-wrapped Muslin Placed in a Plastic Event related

Dust Cover Then Heat Sealed or Bonded

Paper or Polypropylene Peel Pack (Paper, Plastic or Tyvek/Mylar)

Event related and/or per manufacturer's instructions

Rigid Containers, Caskets, etc.

Per manufacturer's instructions

(2) **Note.**

(A) Sterile storage areas shall maintain a:

(i) Temperature of no more than seventy-five degrees Fahrenheit (75°F); and

(ii) Relative humidity of no more than seventy percent (70%).

(B) Ventilation shall:

(i) Be ten (10) air changes per hour; and

(ii) Follow clean-to-dirty flow.

(C) The interior of the dust cover shall not be considered sterile.

(D) Packages that are wet, dropped on the floor, compressed, or torn shall be rejected.

(E) The lot number or control number and expiration statement shall be visible through the package or another tag shall be placed on the outside.

(F)(i)(a) Containers for sterilization systems shall be scientifically proven suitable for the specific sterilization cycle used.

(b) The container system shall be verified as the correct one for the cycle.

(ii) Manufacturer's instructions shall be followed.

(G) Double-wrapped shall mean the end results of the wrapping technique will yield a two-ply covering.

(H) The date of sterilization and load control number shall be placed on each sterilized pack.

(o)(1) Immediate use or “flash” (autoclaving) shall be restricted to unplanned or emergency situations.

(2) Flash sterilization shall never be used as a convenience to compensate for inadequate inventories of instruments or implantables.

(3) Flash sterilization of implantables shall be restricted to the direst circumstances.

(p) Items that are to be immediate use flash-sterilized shall be cleaned and decontaminated before the sterilization process.

(q)(1) Traffic areas in which immediate use or flash sterilization is carried out shall be restricted to authorized personnel wearing surgical attire consisting of:

- (A) Surgical scrubs;
- (B) Shoe covers;
- (C) Masks; and
- (D) Hair covers.

(2) The sterilizer shall not be located adjacent to any potential sources of contamination such as:

- (A) Scrub sinks;
- (B) Clinical sinks or hoppers;
- (C) Wash sinks;
- (D) Linen; or
- (E) Trash disposal areas.

(r) For immediate use or flash sterilization, minimal time at effective temperature shall conform to the following:

AUTOCLAVE	LOA	MINIMAL TIME AT TEMPERATURE
Gravity	Nonporous (Simple Metal Instruments)	3 minutes at 132EC (270EF)

Gravity	Porous (Towels, Rubber, Plastic) Nonporous Mix	10 minutes at 132EC (270EF)
Gravity	Nonporous with Lumens, Deep Grooves, Sliding Parts	10 minutes at 132EC (270EF)
Gravity/Prevacuum	Complex Devices, Air-powered Drills	Per Manufacturer's Instructions
Prevacuum	Nonporous	3 minutes at 132EC (270EF)
Prevacuum	Porous/Nonporous	4 minutes at 132EC (270EF)

(s)(1)(A) Items that previously have been packaged, sterilized, and issued but not used may be returned to the sterile storage area if:

- (i) The integrity of the packaging has not been compromised; and
- (ii) There is no evidence of contamination.

(B) Such items may be dispensed when needed.

(2) Items that previously have been packaged, sterilized, and issued to the patient care units or other areas where the environment is not controlled shall be:

- (A) Discarded if they are single-use items; or
- (B) Unwrapped and reprocessed through decontamination if they are

reusable.

(t)(1) Sterile materials shall be stored:

- (A) Eight to ten inches (8" – 10") from the floor;
- (B) At least eighteen inches (18") from the ceiling; and
- (C) At least two inches (2") from outside walls.

(2) Items shall be positioned so that:

- (A) Packages are not crushed, bent, compressed, or punctured; and
- (B) Sterility is not compromised.

(u) All sterilization techniques other than steam (plasma, ethylene oxide, chemical, etc.) shall:

- (1) Follow the manufacturer's directions; and
- (2) Meet all state and federal regulations.

20 CAR § 43-134. Specialized services — Respiratory care.

(a) Respiratory care services shall be under the direction of a physician member of the medical staff.

(b) Respiratory care services, including equipment, shall be supervised by a qualified and trained respiratory therapist.

(c) There shall be sufficient personnel qualified and trained in respiratory care to provide respiratory care services:

(1) Services may be performed by an assistant only when a qualified and trained respiratory therapist is readily available for consultation; and

(2) Personnel qualified and trained in respiratory care shall be on the premises whenever continuous ventilatory support is provided to patients.

(d) All respiratory care personnel shall maintain competency in:

- (1) Life support measures;
- (2) Isolation techniques; and
- (3) Safety techniques for oxygen and oxygen equipment.

(e)(1) The policy and procedure manual shall have evidence of ongoing review and/or revision.

(2) The first page of the manual shall have the:

- (A) Annual review date; and
- (B) Signature of the department supervisor and/or person or persons conducting the review.

(f) Policies and procedures shall include:

- (1) Job descriptions;
- (2) Documentation verified by the physician director of who may:
 - (A) Perform special procedures; and

- (B) Give patient instructions;
 - (3) Safety practices;
 - (4) Handling, storage, and dispensing of therapeutic gases;
 - (5) Infection prevention and control measures;
 - (6) Assembly and operation of equipment;
 - (7) Respiratory care services provided and a list of services shall be available to the medical staff;
 - (8) Steps to take in the event of an adverse reaction;
 - (9) Cleaning, disinfecting, and sterilizing procedures; and
 - (10) Orientation policies for new employees.
- (g)(1) Clinically relevant educational programs shall be conducted on a regularly scheduled basis of not fewer than twelve (12) per year.
- (2) There shall be evidence of:
 - (A) Program dates;
 - (B) Attendance; and
 - (C) Subject matter.
 - (h) If arterial blood gases are performed, the respiratory care department shall:
 - (1) Subscribe to a nationally recognized proficiency testing program for blood gases; and
 - (2) Meet the quality control requirements for clinical laboratories.
 - (i)(1) The respiratory care service shall have sufficient equipment and adequate facilities appropriate for safety and effective provision of care.
 - (2) Equipment shall be serviced, calibrated, and operated according to manufacturers' directions.
 - (3) An approved safety system shall be used with therapeutic gases.
 - (4) Resuscitation, ventilatory, and oxygenation support equipment shall be available for patients of all sizes.
 - (5) Ventilators for continuous assistance or controlled breathing shall be equipped with alarm systems.

(6) A preventive maintenance program shall be implemented and records maintained for the life of the equipment.

(j) All respiratory care prescription/work requests shall specify:

(1) The type, frequency, and duration of each treatment; and

(2) As required, the:

(A) Type and dose of medication; and

(B) Type of diluent and oxygen or medical air.

(k)(1) Respiratory care reports of blood gas results shall be:

(A) Prepared in duplicate; and

(B) Signed by the therapist responsible for the procedure/test.

(2) The original shall be placed in the patient's medical record and the copy retained in the department file.

(l)(1) Accurate records shall be maintained regarding the type and duration of each treatment given.

(2) These records shall be correlated with the patient's medical record.

(m) Respiratory care documentation for each patient shall include:

(1) Current written plan of care to include goals and objectives;

(2) Instructions to patient or patient's family; and

(3) Type and duration of the treatment given.

(n) When oxygen is being administered to a patient:

(1) Patients, visitors, and personnel shall be apprised of the fire hazard; and

(2) If the patient is in a tent, alcohol or rub-on lotion shall not be used.

(o) Oxygen shall be humidified in accordance with physician's orders.

(p)(1) If reusable reservoirs are used to humidify the oxygen, the reservoirs shall be cleaned and disinfected to a high level of disinfection.

(2) A high-level disinfection can be expected to kill all microorganisms with the exception of high numbers of bacterial endospores.

(3) Only sterile solutions and diluents shall be used in humidification and nebulizing equipment.

(4) Nebulizers, inline and hand-held, between treatments on the same patient shall be disinfected to a high level and rinsed in sterile water or, if a small-volume medication nebulizer, air-dried.

(5) All other semicritical equipment shall be cleaned and disinfected in accordance with the Centers for Disease Control and Prevention's guidelines.

(q) After use, all equipment shall be returned to a central location for thorough cleaning, servicing, and disinfecting before use on another patient.

(r) There shall be an ongoing QA/PI program.

(s) Contracted respiratory care services shall be under current agreement and the contractor shall fulfill all requirements of this section.

(t) **Note.** The National Fire Protection Association Vol. 99, Health Care Facilities, is a mandatory reference for developing safety rules for respiratory care services.

20 CAR § 43-135. Specialized service — Emergency services.

(a) **Note.** Federal Emergency Medical Treatment & Labor Act, 42 U.S.C. § 1395dd requirements apply.

(b)(1) Every licensed hospital shall have a dedicated emergency department.

(2) The following hospitals are excepted:

- (A) Psychiatric hospitals;
- (B) Rehabilitation hospitals;
- (C) Long-term acute care hospitals; and
- (D) Prison hospitals.

(c) The hospital's emergency department shall have organized services, procedures, and nationally recognized protocols for emergencies.

(d)(1) Diagnostic and treatment equipment, medications, supplies, and space shall be adequate in terms of the size and scope of services provided.

(2) Resuscitation and life support equipment shall include but not be limited to:

- (A) Airway control and ventilation equipment including:
 - (i) Laryngoscope and endotracheal tubes;

- (ii) Valve-mask resuscitator;
- (iii) Sources of oxygen;
- (iv) Pulse oximeter; and
- (v) CO2 monitoring;
- (B) Suction devices;
- (C) Standard IV fluids and administration devices, including IV catheters;
- (D) Intravenous fluid and blood warmers;
- (E) Sterile surgical sets for standard ED procedures;
- (F) Gastric lavage equipment; and
- (G) Blood pressure monitoring equipment.

(e)(1) Each emergency department shall have diagnostic imaging and diagnostic laboratory capabilities available twenty-four (24) hours per day, seven (7) days per week.

(2) Such laboratory services shall include:

(A) Standard analyses of:

- (i) Blood;
- (ii) Urine; and
- (iii) Other body fluids;

(B) Blood typing and crossmatching, or process for emergent blood transfusion;

(C) Coagulation studies;

(D) Comprehensive blood bank or access to:

- (i) A community central blood bank; and
- (ii) Adequate hospital storage facilities; and

(E) Blood gases and pH determination.

(f) An inventory list of all supplies and equipment, including all items on the "crash cart", shall be checked each shift and after each use.

(g) The location and telephone number of the nearest poison control center and a list of poison antidotes shall be posted in the emergency department.

(h) **Screening examination.**

(1) Each patient presenting to the emergency department (ED) shall have a medical screening examination by qualified medical personnel.

(2) The examination shall be completely documented.

(i) Treatment and disposition.

(1)(A) If a patient is screened as having an emergency medical condition, a physician shall be contacted to discuss the assessment findings and patient's condition.

(B) A physician shall determine disposition of the patient.

(2)(A) If a patient is screened as having a nonemergency medical condition, a hospital may allow treatment and disposition of the patient by a:

(i) Physician; or

(ii) Nonphysician licensed medical professional.

(B) This individual must be appropriately credentialed by the medical staff with approval by the governing body to provide nonemergent medical care in the emergency department.

(j) Physician availability.

(1) Arrangements shall be provided, such as a duty or on-call roster, to ensure a physician is available for all emergency patients as determined by the screening examination.

(2) Arrangements shall be made for obtaining specialized medical services.

(k) Staffing.

(1) The emergency service shall be under the supervision of a registered nurse.

(2) All patient care personnel assigned to the emergency department shall:

(A) Receive orientation; and

(B) Be competent in life support measures.

(3) An advanced cardiac life support or pediatric advanced life support, as appropriate, trained person shall be in-house and immediately available.

(4)(A) The registered nurse shall assume the responsibility for the nursing functions of the emergency services.

(B) This includes:

- (i) Supervision;
- (ii) Evaluation of the patient's emergency nursing care needs;
- (iii) The assignment of nursing care for each patient to other nursing personnel in accordance with the:
 - (a) Patient's needs; and
 - (b) Preparation and competence of the nursing staff;
- (iv) Supplies and equipment;
- (v) The emergency department record (see 20 CAR § 43-106, general administration, and 20 CAR § 43-114, medical record requirements for outpatient services, emergency room, and observation services); and
- (vi) Maintenance of an emergency department log.

(5) **Emergency medical technician (EMT).** Pursuant to the Emergency Medical Services Act, Arkansas Code § 20-13-201 et seq., if a hospital allows an Arkansas-certified emergency medical technician to perform specified procedures within the emergency room or be a member of a hospital code team the following action shall be taken:

(A)(i) The medical staff shall approve the privileges granted to the individual EMT with concurrence of the hospital's governing body.

(ii) Specific policies governing the supervision and the procedures to be performed by an EMT shall be:

(a) Developed by the medical staff; and

(b) Approved by the hospital's governing body.

(iii) In no event shall an EMT perform a procedure that he or she is not certified to do by the Division of Emergency Medical Services of the Department of Health;

(B) Approved EMTs shall function in accordance with physician's orders and under the direct supervision of either the physician or registered nurse responsible for emergency services;

(C) Students in EMT training programs approved by the Division of Emergency Medical Services of the Department of Health shall be trained by qualified instructors within the hospital under guidelines:

- (i) Established by the medical staff; and
- (ii) Approved by the governing body; and

(D) A roster with the delineation of privileges shall be maintained and readily available.

(l) **Medications.** See 20 CAR § 43-111, medications, and 20 CAR § 43-115, pharmacy.)

(m) **Off-campus emergency departments (off-campus EDs).**

(1) Off-campus EDs shall meet all requirements for hospital EDs.

(2) Off-campus EDs shall:

(A) Function as a department of the parent hospital;

(B) Be fully integrated into the parent hospital's systems and operations:

(i) Medical staff must be part of the parent hospital's single organized medical staff;

(ii) Nursing personnel must be part of the hospital's single organized nursing service;

(iii) Emergency laboratory and imaging services must be available twenty-four (24) hours per day, seven (7) days per week;

(iv) Quality assessment/performance improvement (QAPI) program must be integrated into the parent hospital's QAPI program;

(v) Records must be maintained as part of the hospital's single medical record system;

(vi) Infection prevention and control practices must meet the requirements of the parent hospital's infection control policies and practices;

(vii) Emergency services must meet accepted standards of practice for hospital emergency departments; and

(viii) Patients who require further care must have access to all services of the main hospital; and

(C) Be open twenty-four (24) hours per day, seven (7) days per week.

(n) **Emergency services facility.**

(1) The Department of Health may license under Arkansas Code § 20-9-218 hospitals that have discontinued inpatient services to continue to provide emergency services if there is no other hospital emergency service in the community.

(2) The emergency services facility shall be subject to inspection and to all other provisions of Arkansas Code § 20-9-201 et seq., and the Emergency Medical Services Act, Arkansas Code § 20-13-201 et seq., as amended.

(3) The emergency services facility shall have agreements with licensed hospitals to accept patients who are in need of inpatient hospital services.

(4) An emergency facility shall not have licensed inpatient beds, however, at least one (1) holding/observation bed shall be provided for patient use not to exceed twenty-four (24) hours.

(5)(A) Emergency service facilities shall provide or contract to provide emergency ambulance services licensed by the Department of Health that include radio communication and patient telemetry.

(B) It is further required that contractual agreements be made for patient air transport services.

(6) Policies and procedures shall be developed and approved by the Division of Health Facilities Services prior to issuance of a license, and the facility may not provide services without a license.

(7)(A) Clinically relevant educational programs shall be conducted on a regularly scheduled basis of not fewer than twelve (12) per year.

(B) There shall be evidence of:

- (i) Program dates;
- (ii) Attendance; and
- (iii) Subject matter.

(8) There shall be an ongoing QA/PI program that is specific to the patient care administered.

20 CAR § 43-136. Specialized service — Psychiatric services.

(a) Psychiatric care units in general hospitals shall meet the construction requirements of 20 CAR § 43-147, physical facilities — psychiatric nursing unit, and shall in all respects comply with the requirements of 20 CAR § 43-143, physical facilities, patient accommodations — adult medical, surgical — communicable or pulmonary disease, except furniture, equipment, and supplies may be modified by the attending physician on an individual patient basis as verified by signed orders.

(b) General requirements.

(1) Each psychiatric care unit shall have a written plan describing the organization of services or the arrangement for the provision of such services to meet patient needs.

(2) The services shall include, but not be limited to:

- (A) Diagnostic evaluation;
- (B) Individual or group therapy;
- (C) Consultation; and
- (D) Rehabilitation.

(3) The unit shall be under the direction and management of a psychiatrist who is:

(A) Qualified by training and experience for examination by the American Board of Psychiatry and Neurology, Inc., or the American Osteopathic Board of Neurology and Psychiatry; and

(B) Licensed in the State of Arkansas.

(4) The program director of the unit shall be an individual with at least two (2) years of administrative experience.

(5) The unit shall furnish, through the use of qualified personnel:

- (A) Psychological services;
- (B) Social work services;
- (C) Occupational therapy;
- (D) Recreational therapy; and
- (E) Psychiatric nursing.

(6)(A) The unit shall have a qualified director of nursing with a master's degree or be qualified by education and experience in the care of individuals with mental illness.

(B) If the director does not meet the qualifications, there shall be regular documented consultation by a qualified registered nurse.

(7)(A) Staffing for the unit shall ensure the presence in the unit of a registered nurse at all times.

(B) There shall be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the care necessary under each patient's active treatment program.

(8) The unit shall provide or have available psychological services to meet the needs of the patients.

(9) There shall be a social service staff to provide services in accordance with:

(A) Accepted standards of practice; and

(B) Established policies and procedures.

(10)(A) The unit shall provide a therapeutic activities program.

(B) The program shall be:

(i) Appropriate to the needs and interests of the patients; and

(ii) Directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(11) There shall be a procedure for referrals for needed services.

(12)(A) There shall be adequate space, equipment, and supplies for services to be provided effectively and efficiently in functional surroundings that are readily accessible to the patients.

(B) All space, equipment, and facilities, both within the psychiatric facility and those utilized outside the facility, shall:

(i) Be well maintained; and

(ii) Meet applicable federal, state, and local requirements for:

(a) Safety;

(b) Fire;

(c) Health; and

(d) Sanitation.

(13)(A) Policies and procedures shall have evidence of ongoing review and/or revision.

(B) The first page of each manual shall have the:

(i) Annual review date; and

(ii) Signature of the department director and/or person or persons conducting the review.

(14)(A) Clinically relevant educational programs shall be conducted on a regularly scheduled basis of not fewer than twelve (12) per year.

(B) There shall be evidence of:

(i) Program dates;

(ii) Attendance; and

(iii) Subject matter.

(15)(A) Staff meetings shall be held at least monthly.

(B) Dated minutes of each meeting shall be kept in writing.

(16) There shall be an ongoing program for orientation of staff.

(17) All psychiatric services personnel shall maintain competency in life support measures.

(18) There shall be an ongoing QA/PI program.

(c) Medical records shall include at least:

(1) Identification data including patient's legal status;

(2) Admitting psychiatric diagnosis as well as diagnoses of medical problems;

(3) Reason for the patient's admission;

(4) Social service records including:

(A) Reports of interviews with patients, family members, and others; and

(B) A social history and assessment;

(5)(A) Psychiatric evaluation.

(B) See 20 CAR § 43-114, medical record requirements for outpatient services, emergency room, and observation services; and

(6)(A) Treatment plan.

(B) See 20 CAR § 43-114, medical record requirements for outpatient services, emergency room, and observation services.

(d) **Medications.** See 20 CAR § 43-115, pharmacy.

(e) **Food and nutritional services.** See 20 CAR § 43-116, food and nutrition services.

(f) Organization of psychiatric nursing units and services in general hospitals.

(1) Medical direction shall be provided by a qualified psychiatrist and under the supervision of a registered nurse qualified by training and experience in psychiatric nursing.

(2) In addition to the requirements set forth for nursing services in 20 CAR § 43-110, patient care service, policies and procedures shall be developed specific to the care of the psychiatric patient.

(g) Supplies and equipment shall be commensurate with the types of services offered.

(h) **Medical records.** See 20 CAR § 43-114, medical record requirements for outpatient services, emergency room, and observation services.

20 CAR § 43-137. Specialized service — Care of patients with pulmonary disease in critical access hospitals.

In addition to the patient care services requirements set forth in 20 CAR § 43-110, the policies and procedures shall include specialized procedures specific to respiratory disease patients and shall include:

- (1) Collection of sputum;
- (2) Utilization of respiratory care;
- (3) Skin test procedures;
- (4) Tuberculosis control program for personnel;
- (5) Follow-up service for patients after discharge from the hospital; and
- (6) Provision for individual patient's plan of care.

20 CAR § 43-138. Outpatient psychiatric centers.

(a)(1) Any facility in which psychiatric services are offered for a period of eight (8) to sixteen (16) hours a day and where, in the opinion of the attending psychiatrist, hospitalization as defined in the present licensure law is not necessary, is considered an outpatient psychiatric facility.

(2) This definition does not include community mental health clinics and centers as they now exist.

(3) Such facilities shall conform with applicable sections if those services are provided within the facility.

(4) Such facilities shall conform with applicable sections of 20 CAR § 43-174, physical facilities — outpatient care facilities.

(b) General requirements.

(1) Each psychiatric facility shall have a written plan describing the:

(A) Organization of outpatient services; or

(B) Arrangement for the provision of such services to meet patient needs.

(2) The outpatient services shall include, but not be limited to:

(A) Diagnostic evaluation;

(B) Individual or group therapy;

(C) Consultation; and

(D) Rehabilitation.

(3) The center shall be under the direction and management of a psychiatrist who is:

(A) Qualified by training and experience requirements for examination by the American Board of Psychiatry and Neurology, Inc., or the American Osteopathic Board of Neurology and Psychiatry; and

(B) Licensed in the State of Arkansas.

(4) The program director of the outpatient center shall be an individual with at least two (2) years of administrative experience.

(5) The center shall furnish, through the use of qualified personnel:

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- (A) Psychological services;
- (B) Social work services;
- (C) Occupational therapy;
- (D) Recreational therapy; and
- (E) Psychiatric nursing.

(6)(A) The center shall have a qualified director of nursing:

- (i) With a master's degree; or
- (ii) Qualified by education and experience in the care of individuals

with mental illness.

(B) If the director does not meet the qualifications, there shall be regular documented consultation by a qualified registered nurse.

(7)(A) Staffing for the center shall ensure the presence in the center of a registered nurse during the hours the unit is open.

(B) There shall be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the care necessary under each patient's active treatment program.

(8) The center shall provide or have available psychological services to meet the needs of the patients.

(9) There shall be a social service staff to provide services in accordance with:

- (A) Accepted standards of practice; and
- (B) Established policies and procedures.

(10)(A) The center shall provide a therapeutic activities program.

(B) The program shall be:

- (i) Appropriate to the needs and interests of the patients; and
- (ii) Directed toward restoring and maintaining optimal levels of

physical and psychosocial functioning.

(11) There shall be a procedure for referrals for needed services that are not provided directly by the facility.

(12)(A) There shall be adequate space, equipment, and supplies for outpatient services to be provided effectively and efficiently in functional surroundings that are readily accessible and acceptable to the patients and community services.

(B) All space, equipment, and facilities both within the psychiatric facility and those utilized outside the facility shall:

- (i) Be well maintained; and
- (ii) Meet applicable federal, state, and local requirements for:
 - (a) Safety;
 - (b) Fire;
 - (c) Health; and
 - (d) Sanitation.

(13)(A) Policies and procedures shall have evidence of ongoing review and/or revision.

(B) The first page of each manual shall have the:

- (i) Annual review date; and
- (ii) Signature of the department supervisor and/or person or persons conducting the review.

(14)(A) Clinically relevant educational program shall be conducted on a regularly scheduled basis of not fewer than twelve (12) per year.

(B) There shall be evidence of:

- (i) Program dates;
- (ii) Attendance; and
- (iii) Subject matter.

(15)(A) Regular staff meetings shall be held at least monthly.

(B) Dated minutes of each meeting shall be kept in writing.

(16) There shall be an ongoing program for orientation of staff.

(17) There shall be an ongoing QA/PI program.

(c) Medical records shall include at least:

- (1) Identification data including patient's legal status;
- (2) Admitting psychiatric diagnosis as well as diagnoses of medical problems;

- (3) The reasons for the patient's admission to this level of care;
 - (4) Social service records including:
 - (A) Reports of interviews with patients, family members, and others; and
 - (B) A social history and assessment;
 - (5) Psychiatric evaluation (see 20 CAR § 43-136, specialized service — psychiatric services); and
 - (6) Treatment plan (see 20 CAR § 43-136, specialized service — psychiatric services).
- (d) **Medications.** Outpatient services utilizing medications in therapeutic programs shall fulfill the requirements in 20 CAR § 43-115, pharmacy.
- (e) **Food and nutritional services.** See 20 CAR § 43-116, food and nutrition services.
- (f) **Physical facilities.** The outpatient psychiatric centers shall comply with 20 CAR § 43-174, physical facilities — outpatient care facilities.

20 CAR § 43-139. Rehabilitation hospitals and units.

(a) General requirements.

- (1)(A) "Rehabilitation hospital" means a hospital or a distinct part of a hospital as designated in 20 CAR § 43-102, definitions, that:
- (i) Is used for the primary purpose of providing rehabilitative services as so defined; and
 - (ii) Shall comply with 20 CAR §§ 43-101 – 43-137.
- (B) Each hospital or unit shall have the capability of providing or arranging for emergency services twenty-four (24) hours per day, seven (7) days per week.
- (2)(A) Any comprehensive physical rehabilitative program shall provide through the use of qualified professional personnel, at a minimum, the following clinical services:
- (i) Physical therapy;
 - (ii) Occupational therapy;
 - (iii) Speech therapy; and

(iv) Social services or psychological services.

(B) **Note.** May be provided under contract or arrangement on an as-needed basis.

(3) A physician qualified by training, experience, and knowledge of rehabilitative medicine shall be appointed as the medical director.

(4)(A) Nursing services shall be under the direct supervision of a registered nurse who:

(i) Has a master's degree; or

(ii) Is qualified by education and experience in rehabilitative nursing.

(B) If the registered nurse does not have the required credentials, a master's degree-prepared registered nurse shall be available as a consultant.

(C) The number of registered nurses, licensed practical nurses, and other nursing personnel shall be adequate to formulate and carry out the nursing components of the individual treatment plan for each patient.

(D) There shall be a registered nurse on duty twenty-four (24) hours per day, seven (7) days per week, to:

(i) Plan, assign, supervise, and evaluate nursing care; and

(ii) Provide for the delivery of nursing care to patients.

(5)(A) A physician licensed in the State of Arkansas shall be responsible for each patient's general medical condition as needed.

(B) Medical services shall be available twenty-four (24) hours per day, seven (7) days per week as needed.

(C) Upon admission there shall be written orders for the immediate care of the patient.

(6)(A) Policies and procedures shall be developed.

(B) The manual shall have evidence of ongoing review and/or revision.

(C) The first page of the manual shall have the:

(i) Annual review date; and

(ii) Signature of the department supervisor and/or person or persons conducting the review.

(7)(A) Clinically relevant educational programs shall be conducted on a regularly scheduled basis of not fewer than twelve (12) per year.

(B) There shall be evidence of:

- (i) Program dates;
- (ii) Attendance; and
- (iii) Subject matter.

(8)(A) Regular staff meetings shall be held at least monthly.

(B) Dated minutes of each meeting shall be kept in writing.

(9) There shall be an ongoing QA/PI program.

(b) Special medical record requirements.

(1) Refer also to 20 CAR § 43-113, Health Information Services.

(2) The medical record shall include:

(A) Reason for:

- (i) Referral to physical rehabilitation services; or
- (ii) Admission to the comprehensive physical rehabilitation program;

(B) History and physical examination including patient's:

- (i) Clinical condition;
- (ii) Functional strengths and limitations;
- (iii) Indications and contraindications for specific physical

rehabilitative services; and

(iv) Prognosis;

(C) Goals of treatment and the treatment plan, including:

(i) Any problem that may affect the outcome of physical rehabilitation services; and

(ii) Criteria for the discontinuation of services;

(D)(i) Interdisciplinary treatment plans to include:

- (a) Measurable goals of treatment; and
- (b) Criteria for discharge.

(ii) The plan shall include ongoing assessments as required by the patient's medical condition.

(iii) Documentation of patient and family in the:

(a) Development of the treatment plan;

(b) Resolution of problems; and

(c) Rehabilitation potential;

(E) A discharge summary that includes recommendations for further care;

and

(F)(i) Patient evaluation procedures, including treatment plan for each patient based on the functional assessment and evaluation.

(ii) The initial treatment plan shall be developed within twenty-four (24) hours, and a comprehensive individualized plan:

(a) Developed no later than one (1) week after admission; and

(b) Updated at least monthly.

(iii) The plan shall state the rehabilitative problem, goals, and required therapeutic services, as well as:

(a) Prognosis;

(b) Anticipated length of stay; and

(c) Discharge disposition.

(c) **Physical environment.** The rehabilitation facility shall comply with 20 CAR § 43-141, physical environment.

(d) **Physical facilities.** The rehabilitation facility shall comply with 20 CAR § 43-175, physical facilities — rehabilitation facilities.

20 CAR § 43-140. Recuperation centers.

(a) Any facility that includes inpatient beds with an organized medical staff, and with medical services including physician services and continuous nursing services to provide treatment for patients who are not in an acute phase of illness but who currently require primarily convalescent or restorative services, shall:

(1) Be considered a recuperation center; and

(2) Comply with applicable sections, 20 CAR §§ 43-101 – 43-171.

(b) Quality assurance/performance improvement, infection prevention and control, pharmacy and therapeutics, and utilization review.

(1)(A) The recuperation center shall maintain a Quality Assurance/Performance Improvement Committee consisting of the nurse manager, medical director, and at least three (3) other members of the center's staff that shall meet at least quarterly to provide oversight and direction for the center's quality assurance/performance improvement activities.

(B) Minutes of the Quality Assurance/Performance Improvement Committee shall be maintained.

(2)(A) QA/PI activities shall include ongoing monitoring with:

- (i) Identification of opportunities for improvement;
- (ii) Actions taken; and
- (iii) Evaluation of the results of actions.

(B) QA/PI activities shall be reported at least quarterly to the medical staff and governing body through the hospital-wide QA/PI program.

(3)(A) Reporting of all infection prevention and control, medication, and utilization review issues specific to the center shall be evident in the minutes of the hospital-wide Infection Prevention and Control, Pharmacy and Therapeutics, and Utilization Review Committees.

(B) Frequency of reporting shall be defined in policies and procedures consistent with state laws.

(c) Patient identification.

- (1) Patient armbands shall not be routinely used.
- (2) Reasonable measures shall be used to identify patients.

(d) Restraints. See 20 CAR § 43-112, restraints.

(e) Documentation requirements.

(1) An assessment of the patient's needs shall be completed by a registered nurse on admission.

(2) Each assessment shall be coordinated with all health professionals.

(3)(A) The interdisciplinary team shall develop a comprehensive care plan based on the patient's:

- (i) Identified needs;
- (ii) Measurable goals of treatment;
- (iii) Methods of intervention; and
- (iv) Documentation of resolution or continuance.

(B) There shall be documentation of the patient's and family's participation in the development of the care plan.

(4) Verbal/telephone orders shall be:

- (A) Reduced to writing; and
- (B) Countersigned by the physician.

(f) **Physical environment.** The requirements in 20 CAR § 43-143, physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease, shall apply to recuperation centers with the following exceptions:

(1) The patient dining, recreation, and day room or rooms:

- (A) May be in separate or adjoining rooms; and
- (B) Shall have a total of thirty-five square feet (35 sq. ft.) per patient bed;

and

(2)(A) Patient corridors shall have handrails on both sides of the corridors.

(B) A clear distance of one and one-half inches (1 1/2") shall be provided between the handrail and the wall.

(C) The top of the gripping surface of handrails shall be thirty-two inches (32") minimum and thirty-six inches (36") maximum above the finish floor.

(D) Ends of handrails and grab bars shall be constructed to prevent snagging the clothes of patients.

(E) **Exception.** Special care areas such as those serving children.

(g) **Health Information Services.** Applicable parts of:

- (1) 20 CAR § 43-113(d), Health Information Services; and
- (2) 20 CAR § 43-114, medical record requirements for outpatient services, emergency room, and observation services.

(h) **Nursing services.** A registered nurse shall observe each patient at least once per shift and the observations shall be documented in the patient's medical record.

20 CAR § 43-141. Physical environment.

(a) Building and grounds.

(1) The building and equipment shall be maintained in a state of good repair at all times.

(2) Facilities and their premises shall be kept clean, neat, and free of litter and rubbish.

(3) Rooms for gas-fired equipment shall not be used for storage except for noncombustible materials.

(4) Portable equipment shall be:

(A) Supervised by the department having control of such equipment; and

(B) Stored in areas that are not accessible to patients, visitors, or untrained personnel.

(5)(A) Exit access corridors shall be maintained clear and unobstructed of stationary and nonpatient-related portable equipment.

(B) Stationary or portable nonpatient-care furnishings or equipment shall not be stored in an exit access corridor.

(C) Any portable equipment such as a gurney, wheelchair, linen care, etc., that is not actively used within a thirty-minute time period is considered "stored".

(D) The facility's fire plan and training program shall address the relocation of these items during a fire.

(E)(i) Exit access corridors for healthcare occupancies are those aisles, corridors, and ramps required for exit access that are located outside of a:

(a) Suite of sleeping rooms greater than five thousand square feet (5,000 sq. ft.); or

(b) Suite of rooms greater than ten thousand square feet (10,000 sq. ft.).

(ii) "Area" is defined as occupiable net floor space.

(F) Encroachments on the width of the means of egress in an exit access corridor by stationary objects or furnishings shall not be allowed.

(G) The width of the means of egress in an exit access corridor shall be defined by physical means such as:

- (i) Corridor walls;
- (ii) Columns; or
- (iii) Other approved methods.

(H) The means of egress may provide both visual and physical barrier design characteristics conducive to establishing a common egress that provides for either:

- (i) A change in floor texture; or
- (ii) Self-illumination in the dark.

(I) **Alternative consideration.** Means of Egress Requirements for Health Care Occupancies of NFPA 101 or equivalency per 20 CAR § 43-142.

(6)(A) Each hospital shall develop a written preventive maintenance plan.

(B) This plan shall be available to the Department of Health for review at any time.

(C) Such plans shall provide for maintenance as recommended by:

- (i) Manufacturer;
- (ii) Applicable codes; or
- (iii) Designer.

(7) The handwashing facilities in visitors' restrooms and the handwashing facilities used by staff personnel shall be equipped with a soap dispenser and a towel dispenser.

(8)(A) A supply of hot water for patient use shall be available at all times.

(B) A weekly hot water temperature log shall be maintained.

(9)(A) Heating, ventilating, and air conditioning systems shall be operated and maintained in a manner to provide a comfortable and safe environment for patients, personnel, and visitors.

(B) An air filter changeout log shall be maintained.

(b) Maintenance and engineering.

(1) The physical plant and equipment maintenance programs shall be under the direction of a person:

- (A) Qualified by training and/or experience; and
- (B) Licensed where required.

(2) Equipment management program.

(A) There shall be a preventive maintenance program designed to ensure the electrically powered patient care equipment used to monitor, diagnose, or provide therapy performs properly and safely.

(B) This program shall be administered by:

- (i) Individuals qualified through training and/or experience; or
- (ii) Procuring a contractual maintenance agreement.

(C) The following are minimum program elements:

(i) A current list of electrically powered patient care equipment shall be maintained regardless of location or ownership;

(ii)(a) Each device or identical group of devices shall have a procedure establishing minimum criteria against which performance and safety are measured.

(b) The elements of these procedures shall be based on the manufacturer's directions;

(iii) Each device shall be tested at intervals of not more than six (6) months unless there is documented evidence that less frequent testing is justified;

(iv) Historical records documenting acceptable performance as established by the procedures shall be maintained;

(v) A program to identify and repair equipment failures shall be maintained;

(vi) User or owner departments shall be notified of the status of their equipment when it will be out of service more than twenty-four (24) hours;

(vii) There are operator and maintenance instructions for each device or group of similar devices on the electrically powered patient care equipment list; and

(viii)(a) Individuals shall be trained to operate and maintain equipment used in the performance of their duties.

(b) This training shall be documented.

(3) Utilities management program (UMP).

(A) There shall be a preventive maintenance program designed to ensure that the physical plant equipment and building systems perform properly and safely.

(B) This program shall be administered by:

(i) Individuals qualified through training and/or experience; or

(ii) Procuring a contractual agreement.

(C) This program shall consist of at least the following minimum elements:

(i) A list of physical plant equipment and/or building system or systems shall be maintained regardless of location or ownership;

(ii)(a) Equipment and/or building system or systems shall have a procedure establishing minimum criteria against which performance and safety are measured.

(b) The elements of these procedures shall be based on the:

(1) Manufacturer's directions; and/or

(2) Experience of the repair technician or operator;

(iii) Equipment and/or building system or systems shall be tested, serviced, or inspected at intervals of not more than twelve (12) months unless there is documented evidence that less frequent service is justified;

(iv) Historical records documenting acceptable performance as established by the procedures shall be maintained;

(v) A program to identify and repair equipment failures shall be maintained;

(vi) User or owner departments shall be notified of the status of their equipment or system when it will be out of service for more than twenty-four (24) hours;

(vii) There shall be operator and/or maintenance instructions for each piece of equipment or building system on the list; and

(viii)(a) Individuals shall be trained to operate and maintain physical plant equipment and/or building systems.

(b) This training shall be documented.

(4) Life safety management program (LSM).

(A) There shall be a preventive maintenance program designed to ensure that all circuits of fire alarm and detection systems shall be inspected, tested, and maintained in accordance with NFPA 72.

(B) Analog detection devices that provide automatic self-testing are exempt from the quarterly testing requirement.

(C) This program shall be administered by:

(i) Individuals qualified through training and/or experience; or

(ii) Procuring a contractual maintenance agreement.

(D) This program shall consist of the following minimum elements:

(i) A list of all fire protection equipment or component groups shall be maintained;

(ii)(a) Equipment and/or component groups shall have a procedure establishing minimum criteria against which performance and safety are measured.

(b) The elements of these procedures shall be based on the:

(1) Manufacturer's recommendations; and/or

(2) Experience of the repair technician or operator;

(iii) Fans or dampers in air handling and smoke management systems shall be reliable and functional at all times;

(iv)(a) Automatic fire extinguishing systems shall be inspected and tested annually; actual discharge of the fire extinguishing system is not required.

(b) Records documenting acceptable performance as established by the procedures shall be maintained;

(v) A program to identify and repair equipment and/or component group failures shall be maintained;

(vi) Systems for transmitting fire alarms to the local fire department shall be reliable and functional at all times;

(vii) There shall be operator and maintenance instructions for each piece of equipment and/or component group on the list;

(viii) Individuals shall be trained to operate and maintain all equipment and/or component group on the list; and

(ix) Portable fire extinguishers shall be clearly identified.

(5) Emergency procedures program (EPP).

(A) There shall be written emergency procedures or a disaster management plan for utility system disruptions or failures that address the specific and concise procedures to follow in the event of a utility system malfunction or failure of the:

- (i) Water supply;
- (ii) Hot water system;
- (iii) Medical gas system;
- (iv) Sewer system;
- (v) Bulk waste disposal system;
- (vi) Natural gas system;
- (vii) Commercial power system;
- (viii) Communication system;
- (ix) Boiler; or
- (x) Steam delivery system.

(B) These procedures shall be kept separate from all other policy and procedure manuals to facilitate their rapid implementation.

(C) These procedures shall contain but are not limited to the following information:

- (i) A method of obtaining alternative sources of essential utilities;
- (ii) A method of shutoff and location of valves for malfunctioning systems;
- (iii) A method of notification of hospital staff in affected areas; and
- (iv) A method of obtaining repair services.

(6) Policies and procedures shall include job descriptions and orientation practices for employees.

(7)(A) Policies and procedures shall have evidence of ongoing review and/or revision.

(B) The first page of each manual shall have the:

(i) Annual review date; and

(ii) Signature of the department supervisor and/or person or persons conducting the review.

(8)(A) Relevant educational programs shall be conducted at regularly scheduled intervals with no fewer than six (6) per year.

(B) There shall be evidence of:

(i) Program dates;

(ii) Attendance; and

(iii) Subject matter.

(9) The department director shall:

(A) Ensure that all employees annually attend mandatory educational programs on:

(i) Fire safety;

(ii) Back safety;

(iii) Infection prevention and control;

(iv) Universal precautions;

(v) Emergency procedures; and

(vi) Disaster preparedness; or

(B) Make provisions to conduct these departmentally.

(10) There shall be sufficient supervisory and support personnel to provide maintenance services in relation to the:

(A) Size and complexity of the facility; and

(B) Services that are provided.

(11) An ongoing QA/PI program with a liaison with the Infection Prevention and Control and Safety Committees.

(c) Environmental services.

- (1) The environmental services shall be under the direction of a person:
 - (A) Qualified by training and/or experience; and
 - (B) Licensed where required.
- (2) There shall be written policies and procedures that include:
 - (A) Cleaning of the physical plant;
 - (B) The use, care, and cleaning of equipment;
 - (C) Specific cleaning methods used for:
 - (i) Operating rooms;
 - (ii) Delivery rooms;
 - (iii) Nurseries/infant care units;
 - (iv) Emergency rooms;
 - (v) Isolation areas; and
 - (vi) Other units as appropriate;
 - (D) Job descriptions;
 - (E) Orientation practices;
 - (F) Safety practices;
 - (G) Infection prevention and control measures;
 - (H) Methods used for evaluation of cleaning effectiveness;
 - (I) Personal hygiene;
 - (J) The selection of housekeeping and cleaning supplies; and
 - (K) The proper use of housekeeping and cleaning supplies.
- (3)(A) The policy and procedure manual shall have evidence of ongoing review and/or revision.
 - (B) The first page of each manual shall have the:
 - (i) Annual review date; and
 - (ii) Signature of the department and/or person or persons conducting the review.
- (4)(A) Relevant in-service educational programs shall be conducted at regularly scheduled intervals with no fewer than six (6) per year.

(B) There shall be written documentation with:

- (i) Employee signatures;
- (ii) Program title/subject;
- (iii) Presenter;
- (iv) Date; and
- (v) Outline or narrative of presented program.

(5) Expendable supplies (i.e., soap, paper products, etc.) shall be stored in a manner that shall prevent their contamination prior to use.

(6) Solutions, cleaning compounds, disinfectants, vermin control chemicals, and all other potentially hazardous substances that are used in connection with environmental services shall be:

(A) Kept in containers that accurately reflect at least the following:

- (i) Content name;
- (ii) Concentration of solution; and
- (iii) Expiration date and lot number;

(B)(i) Stored in a secured area.

(ii) Under no circumstances shall these substances be stored in or near food storage or food preparation areas; and

(C)(i) Selected by the director of environmental services or other appointed qualified person.

(ii) The Infection Prevention and Control Committee shall initially approve the list of chemicals used in the facility and, thereafter, any additions or deletions to the list.

(7) A designee from this department shall be a member of the Infection Prevention and Control Committee.

(8) The use of common towels and common drinking utensils shall be prohibited.

(9) Dry or untreated dusting, sweeping, or mopping, except vacuum-type cleaning, shall be prohibited within the facility.

(10) There shall be an ongoing QA/PI program with a mechanism for reporting results.

(d) Linen services.

- (1) Laundry services shall be under the direction of a person:
 - (A) Qualified by training and/or experience; and
 - (B) Licensed where required.
- (2) There shall be sufficient support personnel to provide linen services in relation to the:
 - (A) Size and complexity of the facility; and
 - (B) Services that are provided.
- (3) There shall be written policies and procedures that include:
 - (A) Collection of soiled, wet, and contaminated linen;
 - (B) Transporting of soiled, wet, and contaminated linen to:
 - (i) The laundry service; or
 - (ii) A designated area for commercial pick-up;
 - (C) Storage of soiled, wet, and contaminated linen until laundering or being picked up by the commercial laundry;
 - (D) Storage of clean linen; and
 - (E) Specific laundry requirements (type detergent, sours, bleach, time, and temperatures used) for washing:
 - (i) New linen;
 - (ii) Diapers; and
 - (iii) Soiled, wet, and contaminated linen;
 - (F) Personal hygiene;
 - (G) Evaluation of washing/cleaning effectiveness;
 - (H) Job descriptions;
 - (I) Orientation practices for new employees;
 - (J) Safety practices; and
 - (K) Infection prevention and control measures.

(4)(A) Policies and procedures for linen services shall have evidence of ongoing review and/or revision.

(B) The first page of the manual shall have the:

(i) Annual review date; and

(ii) Signature of the department supervisor and/or person or persons conducting the review.

(5)(A) Relevant in-service educational programs shall be conducted at regularly scheduled intervals with no fewer than six (6) per year.

(B) There shall be written documentation with:

(i) Employee signature;

(ii) Program title/subject;

(iii) Presenter;

(iv) Date; and

(v) Outline or narrative of presented program.

(6) Facility linen service.

(A) Sorting of soiled laundry shall be done in a designated area.

(B) Tables or bins shall be provided for sorting of soiled laundry.

(C) Lint traps shall be:

(i) Provided on dryers; and

(ii) Cleaned regularly.

(D) Prerinsing shall be done in the laundry service, not in:

(i) Showers;

(ii) Bathtubs; or

(iii) Lavatories.

(E) Removal of solid soil shall be done in:

(i) Soiled utility rooms; or

(ii) Rooms that are designated for this purpose.

(F) Patient clothing may be washed in the patient area if a separate equipped laundry room is available.

(G) A rinsing sink shall be provided in the soiled linen area of the laundry.

(H) Hot water supplied to laundry areas shall be in accordance with Table 9 of Appendix A.

(I) Linen contained in hot water-soluble plastic bags identified as being contaminated shall be placed directly into the washing machine without being removed from the bag for sorting.

(J) A lavatory equipped with wrist action controls, a soap dispenser, and a towel dispenser shall be provided in the laundry for use by the personnel.

(K) Personnel with infectious disease or open wounds shall not be permitted in the laundry.

(L) Personnel assigned to laundry duties shall wash their hands:

- (i) After handling wet or soiled laundry;
- (ii) Before leaving the laundry;
- (iii) After using the toilet; and
- (iv) As often as is necessary to maintain good hygiene.

(M) **Note.** Laundry equipment and installation requirements are set forth in 20 CAR § 43-163, physical facilities — linen services.

(7)(A) Soiled linen from isolation areas, surgical cases, etc., shall be placed into impervious bags and, if leakage occurs, bagged into a second bag with proper identification.

(B) Suitable precautions shall be taken in transport, handling, and processing.

(8) Soiled, wet, and contaminated linens shall be transported in a closed container.

(9)(A) Soiled, wet, and contaminated linens shall be stored in closed containers or impervious bags in designated areas off the floor.

(B) Areas for storage of soiled, wet, and contaminated linens shall have forced ventilation to the outside of the building.

(10) All new clothing, linen, and diapers shall be laundered before being used.

(11) There shall be a designated area for the storage of clean linens.

(12) The linen service within the facility shall have a capacity sufficient to process a continuous supply of clean laundry ready for use.

(13)(A) Temperature used in the dryer will depend on the type of fabric.

(B) An employee shall be present at all times when the dryer is in operation.

(14) There shall be an ongoing QA/PI program with a mechanism for reporting results.

(15) Linen service shall include a written contingency plan indicating an alternative provision that may be followed in the event the laundry is unable to meet the production demand of the facility.

(16) Separate containers for the disposal of infectious waste and sharps shall be located in the soiled linen sorting area.

(17) Laundry workers handling infectious linens shall wear protective equipment, including but not limited to:

(A) Waterproof, puncture-resistant gloves;

(B) Protective over-clothing; and

(C) Where necessary, face shields or goggles.

(18) Facilities that do not have linen services:

(A) The facility shall:

(i) Determine that all launderable items are processed in a commercial laundry in accordance with standards set forth in this section;

(ii) Conduct annual onsite inspections of the commercial laundry; and

(iii) Require written verification of compliance by the laundry.

(B) Soiled, wet, and contaminated laundry shall be stored in a the commercial laundry;

(C) A designated clean area shall be:

(i) Provided for receiving clean laundry; and

(ii) Separate from the soiled linen area; and

(D) Clean linen shall be packaged and protected from contamination during transportation and storage.

(19) Refer to 20 CAR § 43-117, infection prevention and control, for additional requirements.

(e) **Safety services.**

(1)(A) There shall be an effective program to enhance safety within the facility and grounds.

(B) The program shall be monitored by a safety committee appointed by the administrator.

(C) Committee members may be selected from areas such as:

- (i) Administration;
- (ii) Nursing;
- (iii) Maintenance;
- (iv) Housekeeping;
- (v) Laboratory;
- (vi) Respiratory care;
- (vii) Rehabilitation services;
- (viii) The medical staff; and
- (ix) Others, as appropriate.

(2)(A) The safety committee shall meet a minimum four (4) times per year to fulfill safety objectives.

(B) Minutes of each meeting shall be recorded and kept in the facility.

(3) The administrator shall designate a specific individual to:

(A) Carry out policies established by the safety committee; and

(B) Gather data for the Safety Committee to study safety-related incidents.

(4)(A) Safety policies and procedures shall have evidence of ongoing review and/or revision.

(B) The first page of each manual shall have the:

(i) Annual review date; and

(ii) Signature of the department supervisor and/or person or persons conducting the review.

- (C) Safety policies and procedures shall include:
 - (i) Facility-wide hazard surveillance program;
 - (ii) Response to medical device recalls and hazard notices;
 - (iii) Safety education;
 - (iv) Reporting of all accidents, injuries, and safety hazards;
 - (v) External and internal disaster plans;
 - (vi) Fire safety; and
 - (vii) Safety devices and operational practices.
- (5) The orientation program for the facility shall include the:
 - (A) Importance of general safety and fire safety; and
 - (B) Responsibility of each individual to the program.
- (6) The Safety Committee shall have the following functions:
 - (A) Monitoring the results of the safety program and analyzing the effectiveness of the program annually;
 - (B) Monitoring fire drills and disaster drills at required intervals;
 - (C) Conclusions, recommendations, and actions of the safety committee shall be reported to the board at a minimum annually; and
 - (D) Ensuring each department or service shall have a safety policy and procedure manual within their own area that:
 - (i) Is a part of the overall facility safety manual; and
 - (ii) Establishes safety policies and procedures specific to each area.
- (7)(A) Fire extinguishers shall be:
 - (i) Provided in adequate numbers of the correct type; and
 - (ii) Properly located and installed.
- (B) Personnel shall be trained in the proper use of fire extinguishers and equipment.
- (C) Personnel shall follow procedures in fire containment and evacuating patients in case of fire or explosion.

(D) There shall be an annual check of all fire extinguishers by qualified persons in accordance with the applicable sections of the National Fire Protection Association's Standard 10 (NFPA 10).

(E) The date the check was made and the initials of the inspector shall be recorded on:

- (i) The fire extinguisher; or
- (ii) A tag attached to the extinguisher.

(8)(A) Any fire or disaster event at the facility shall be reported immediately to the Department of Health by telephone 501-661-2201 during regular working hours or 501-661-2136 after normal working hours, holidays, and weekends.

(B) If any fire or fires or disaster is not reported to the Department of Health, the facility is subject to a fine, refer to 20 CAR § 43-103(j), licensure and codes.

(9) There shall be policies and procedures governing the routine methods of handling and storing flammable and explosive agents, particularly in:

- (A) Operating rooms;
- (B) Delivery rooms;
- (C) Laundries; and
- (D) Areas where oxygen therapy is administered.

(10)(A) There shall be keys available to ensure prompt access to all locked areas.

(B) All doors shall be devised so they can be opened from the inside of the locked area.

(C) Special door locking devices are acceptable in limited areas.

(D) Usage is subject to all codes and regulations.

(11) All required exit doors shall remain unlocked per NFPA requirements.

(12) A list of material safety data sheets (MSDS) for solutions, cleaning compounds, disinfectants, vermin control chemicals, and other potentially hazardous substances used in connection with the facility shall be readily available:

(A) To the Safety Committee, emergency room, and environmental services; and

(B) As directed by facility policy and procedures.

20 CAR § 43-142. Physical facilities.

(a) General considerations.

(1) The requirements set forth herein:

(A) Have been established by the Department of Health; and

(B) Constitute minimum requirements for the design, construction, renovation, and repair of facilities requiring licensure under this part.

(2)(A) Facilities shall be accessible to the public, staff, and patients with physical disabilities.

(B) Minimum requirements shall be those set forth by Title 22, Subchapter B, Building Authority Minimum Standards and Criteria, Part 111 Design Review Section, Accessibility for Individuals with Disabilities Standards, 22 CAR § 111-1001 et seq.

(3)(A) Projects involving renovation and additions to existing facilities shall be programmed and phased to minimize disruption of the existing functions.

(B) Access, exits, and fire protection shall be maintained for the occupants' and the facility's safety.

(4) Codes and standards.

(A) Nothing stated herein shall relieve the owner from compliance with building codes, ordinances, and regulations that are enforced by city, county, or other state jurisdictions.

(B) Where such codes, ordinances, and regulations are not in effect, the owner shall consult the state building codes for all components of the building type that are not specifically covered by these minimum requirements.

(C) In locations where there is a history of tornadoes, floods, earthquakes, or other regional disasters, planning and design shall consider the need to protect the occupants and the facility.

(b) **Occupancy.** Each licensed facility or portion of a licensed facility shall be classified as indicated below:

(1)(A) General hospital.

(B) A facility or portion of a facility licensed by the Department of Health as a general hospital that provides:

(i) For patient care, treatment, or diagnosis on a twenty-four-hour basis; and

(ii) Treatment or anesthesia for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others;

(2)(A) Mobile, transportable, and relocatable unit.

(B) A portion of a facility licensed by the Department of Health that meets the definitions provided in 20 CAR § 43-153 for mobile, transportable, and relocatable units;

(3)(A) Outpatient care facility.

(B)(i) A portion of a facility licensed by the Department of Health that:

(a) Provides patient care, treatment, or diagnosis on a less-than-twenty-four-hour basis; and

(b) Does not provide treatment or anesthesia for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others.

(ii) Outpatient care facilities may be utilized on occasion by hospital inpatients provided that such use is limited to a less-than-twenty-four-hour basis;

(4)(A) Rehabilitation facility.

(B) A facility or portion of a facility licensed by the Department of Health as a rehabilitation facility; and

(5)(A) Nonhealthcare occupancy.

(B) A portion of a licensed facility that does not contain:

(i) Areas intended for patient care, treatment, or diagnosis; and

(ii) Equipment (mechanical, electrical, plumbing, communication, fire alarm, etc.) that serves areas intended for patient:

(a) Care;

(b) Treatment; or

(c) Diagnosis.

(c) **Multiple occupancy.** Facilities may contain more than one (1) occupancy as described above provided each different occupancy is separated from all other occupancies by a two-hour fire-resistive-rated smoke barrier.

(d) **Construction projects.** Each construction project shall be classified as indicated below:

(1)(A) Addition.

(B) A project that increases the floor area of a licensed facility;

(2)(A) Repair.

(B) A project that provides for the repair or renewal of a licensed facility or portion of a licensed facility solely for the purpose of its maintenance; and

(3)(A) Simple renovation.

(B) A project other than repair that meets all of the criteria listed below:

(i) The project does not increase the floor area of a licensed facility;

(ii) The project does not change the occupancy of a:

(a) Licensed facility; or

(b) Portion of a licensed facility;

(iii) The project does not involve more than two (2) smoke compartments; and

(iv) The smoke compartments affected by the project were completely protected by an automatic sprinkler system prior to the project or the project provides for the installation of a complete automatic sprinkler system in all smoke compartments that are affected by the project.

(e) **Applicable requirements based upon occupancy.**

(1) **Existing facilities.** Existing facilities that do not comply with this part shall be permitted to continue in service, provided the lack of conformity with this part does not present a serious hazard to the occupants as determined by:

(A) The Division of Health Facilities Services; or

(B) Other authorities having jurisdiction.

(2) **General hospital.** Facilities or portions of facilities classified as a general hospital occupancy shall be designed, constructed, and renovated in accordance with the sections of this part listed below and all publications and appendices referenced by these sections:

- (A) 20 CAR § 43-141;
- (B) This section;
- (C) 20 CAR §§ 43-143 – 43-152; and
- (D) 20 CAR §§ 43-153 – 43-175.

(3) **Mobile, transportable, and relocatable unit.** Facilities or portions of facilities classified as a mobile, transportable, and relocatable unit occupancy shall be designed, constructed, and renovated in accordance with the sections of this part listed below and all publications and appendices referenced by these sections:

- (A) 20 CAR § 43-141;
- (B) This section; and
- (C) 20 CAR § 43-153.

(4) **Outpatient care facility.** Facilities or portions of facilities classified as an outpatient care facility occupancy shall be designed, constructed, and renovated in accordance with the sections of this part listed below and all publications and appendices referenced by these sections:

- (A) 20 CAR § 43-141;
- (B) This section; and
- (C) 20 CAR § 43-174.

(5) **Rehabilitation facility.** Facilities or portions of facilities classified as an outpatient care facility occupancy shall be designed, constructed, and renovated in accordance with the sections of this part listed below and all publications and appendices referenced by these sections:

- (A) 20 CAR § 43-141;
- (B) This section; and
- (C) 20 CAR § 43-175.

(6) **Nonhealthcare occupancy facilities.** Portions of facilities classified as a nonhealthcare occupancy shall be designed, constructed, and renovated in accordance with the sections of this part listed below and all publications and appendices referenced by these sections:

(A) 20 CAR § 43-141; and

(B) This section.

(f) **Applicable requirements based upon the type of project.**

(1) **General.**

(A)(i) Where renovation work is done within an existing facility, all new work or additions or both shall comply insofar as practical with applicable sections of this part and appropriate sections of the National Fire Protection Association (NFPA) 101 Life Safety Code covering new occupancies.

(ii) Where major structural elements make total compliance impractical or impossible, exceptions will be considered.

(B)(i) In renovation projects and projects involving additions to existing facilities, only that portion of the total facility affected by the project shall comply with applicable sections of this part and with appropriate parts of NFPA 101 covering new occupancies.

(ii) Existing portions of the facility that are not included in the project but essential to the functioning of a complete facility shall comply at a minimum with the appropriate sections of NFPA 101 covering existing occupancies.

(iii) Existing portions of the facility that receive less than substantial amounts of new work shall also comply at a minimum with the appropriate sections of NFPA 101 covering existing occupancies.

(C) Facilities or portions of facilities shall be permitted to be occupied during construction, renovation, and repair only where:

(i) Required means of egress and required fire protection features are in place and continuously maintained for the portion occupied; or

(ii) Alternate life safety measures acceptable to the Division of Health Facilities Services and other authorities having jurisdiction are in place.

(2) Addition, simple renovation, and complex renovation shall be designed, constructed, and renovated in accordance with:

(A) The applicable sections of this part; and

(B) All appendices and publications referenced by these sections.

(3) Repair projects shall be designed and constructed in a manner that does not diminish the safety level that existed prior to the start of the work.

(g) Project review and approval process.

(1) **Coordination.** The Division of Health Facilities Services of the Department of Health will coordinate the review and approval process for all offices of the Department of Health.

(2) Addition or complex renovation projects shall be reviewed and approved by the Division of Health Facilities Services as indicated below.

(A) Drawing review and approval process.

(i) Submission of plan review fee.

(a) A plan review fee in the amount of one percent (1%) of the total cost of construction or five hundred dollars (\$500), whichever is less, shall be paid for the review of plans and specifications.

(b) The plan review fee check is to be made payable to the Department of Health.

(c) A detailed estimate shall accompany the plans unless the maximum fee of five hundred dollars (\$500) is paid.

(ii) Submission of functional program. Refer to subsection (h) of this section.

(iii) Submission of site location. Refer to subsection (i) of this section.

(iv) Submission of preliminary plans. Refer to subsection (j) of this section.

(v) Review of functional program, site location, and preliminary plans. The Division of Health Facilities Services shall review the functional

program, site location, and preliminary plans and forward a written response with comments to the facility.

(vi) **Submission of final construction documents.** Refer to subsection (k) of this section.

(vii) **Review and approval of final construction documents.**

(a) The Division of Health Facilities Services shall:

(1) Review the final construction documents; and

(2) Forward a written response with comments to the facility and the design professional.

(b) The Division of Health Facilities Services shall have a minimum of six (6) weeks to review final construction documents.

(c) The written response shall indicate whether or not the final construction documents are approved.

(d) If the final construction documents are not approved, the written response shall indicate the design modifications required to secure approval.

(viii) Plans may be certified by a licensed architect or professional engineer with respect to compliance with the applicable codes, rules, and standards.

(B) **Approval to begin construction.** Facilities may proceed with addition and complex renovation projects after receiving:

(i) A letter from the Division of Health Facilities Services stating that the final construction documents have been reviewed and approved; and

(ii) Approval from other authorities having jurisdiction.

(C) **Site inspections during construction.** Refer to subsection (l) of this section.

(D) **Final site inspection.** Refer to subsection (m) of this section.

(3) **Repair.** Repair projects do not require review and approval by the Division of Health Facilities Services.

(4) Simple renovation projects submitted to the Division of Health Facilities Services shall be reviewed and approved by the Division of Health Facilities Services as indicated below:

(A) Drawing review and approval process.

(i) Submission of plan review fee.

(a) A plan review fee in the amount of one percent (1%) of the total cost of construction or five hundred dollars (\$500), whichever is less, shall be paid for the review of plans and specifications.

(b) The plan review fee check is to be made payable to the Department of Health.

(c) A detailed estimate shall accompany the plans unless the maximum fee of five hundred dollars (\$500) is paid.

(ii) Submission of functional program. Refer to subsection (h) of this section.

(iii) Submission of final construction documents. Refer to subsection (k) of this section.

(iv) Review and approval of final construction documents.

(a) The Division of Health Facilities Services shall review the final construction documents and forward a written response with comments to the facility.

(b) The Division of Health Facilities Services shall have a minimum of six (6) weeks to review final construction documents.

(c) The written response shall indicate whether or not the final construction documents are approved.

(d) If the final construction documents are not approved, the written response shall indicate the design modifications required to secure approval.

(v) Plans may be certified by a licensed architect or professional engineer with respect to compliance with the applicable codes, rules, and standards;

(B) Approval to begin construction. Facilities may proceed with simple renovation projects after receiving:

(i) A letter from the Division of Health Facilities Services stating that the final construction documents have been reviewed and approved; and

(ii) Approval from other authorities having jurisdiction;

(C) **Site inspections during construction.** Refer to subsection (l) of this section; and

(D) **Final site inspection.** Refer to subsection (m) of this section.

(h) **Functional program.** The facility shall supply for each project, other than a repair project, a functional program that:

- (1) Describes the purpose of the project; and
- (2) Indicates the estimated cost of construction.

(i) **Site location.**

(1) **Location.**

(A) The site of any medical facility should be easily accessible to:

- (i) The community; and
- (ii) Service vehicles such as fire protection apparatus.

(B) Facilities should be located with due regard to the:

(i) Accessibility by public transportation for:

- (a) Patients;
- (b) Staff; and
- (c) Visitors; and

(ii) Availability of competent medical and surgical consultation.

(C)(i) The facility should have security measures for patients, personnel, and the public consistent with the conditions and risks inherent in the location of the facility.

(ii) These measures shall include a program designed to protect human and capital resources.

(D) The facility should be located to provide reliable utilities (water, natural gas, sewer, and electricity).

(E) The site should afford good drainage and shall not be subject to flooding nor be located near insect breeding areas, excessive noise, nor other nuisance producing locations, nor near airports, railways, air pollution, penal institutions (except prison infirmaries), or a cemetery.

(2) **Roads and parking.**

(A)(i) Paved roads and walks shall be provided within the lot lines to provide access to the main entrance and service entrance, including loading and unloading docks for delivery trucks.

(ii) Hospitals having an organized emergency services department shall have the emergency entrance well-marked to facilitate entry from the public roads or streets serving the site.

(iii) Access to the emergency entrance shall not conflict with other vehicular traffic or pedestrian traffic.

(iv) Paved walkways shall be provided for necessary pedestrian traffic.

(B)(i) Each facility shall have parking spaces to satisfy the minimum needs of:

(a) Patients;

(b) Employees;

(c) Staff; and

(d) Visitors.

(ii) In the absence of a formal parking study, each facility shall provide not less than one (1) space for each day shift staff member and employee plus one (1) space for each patient bed.

(iii) This ratio may be reduced in an area convenient to a public transportation system or to a public parking facility:

(a) If proper justification is given; and

(b) Provided that approval of any reduction is obtained from the Department of Health.

(iv) Additional parking shall be required to accommodate outpatient and other services when they are provided.

(v) Space shall be provided for emergency and delivery vehicles.

(3) Subsoil investigation.

(A) Subsoil investigation shall be made to determine the subsurface soil and water conditions.

(B) The investigation shall include a sufficient number of test pits or test borings to determine, in the judgment of the architect and the structural engineer, the true subsurface conditions.

(C) Results of the investigation shall be available in the form of a:

- (i) Soil investigation report; or
- (ii) Foundation engineering report.

(D) The investigation shall:

- (i) Be made in close cooperation with the architect and structural engineer; and
- (ii) Contain detailed recommendations for foundation design and gradings.

(E) The following is a general outline of the suggested scope of soil investigation:

(i)(a) The borings or test pits shall extend into stable soils well below the bottom of any proposed foundations.

(b) A field log of the borings shall be made and the thickness, consistency, and character of each layer recorded;

(ii)(a) The amount and elevation of groundwater encountered in each pit or boring and its probable variation with the seasons and effect on the subsoil shall be determined.

(b) High or low water levels of nearby bodies of water affecting the ground level shall also be determined;

(iii) Laboratory tests shall be performed to determine the safe bearing value and compressibility characteristics of the various strata encountered in each pit or boring;

(iv) Maximum depth of frost penetration below surface of the ground shall be recorded; and

(v) Tests shall be made to determine whether the soil contains alkali in sufficient quantities to affect concrete foundations.

(4) **Approval.** The new building site shall be inspected and approved by the Department of Health before construction begins.

(j) **Preliminary plans.** Preliminary plans submitted to the Division of Health Facilities Services shall include at a minimum the following information:

(1) Floor plans drawn to scale that indicate:

- (A) Room names;
- (B) Room dimensions;
- (C) Corridor dimensions;
- (D) Locations of fire-resistive rated partitions; and
- (E) Locations of rated smoke barriers;

(2) An existing floor plan indicating existing spaces and exits and their relationship to the new construction (renovation projects only);

(3)(A) Building sections that establish the proposed construction type and fire rating.

(B) Sections shall be drawn at a scale sufficiently large to clearly present the proposed construction system;

(4) A site plan that indicates the location of proposed:

- (A) Roads;
- (B) Walks;
- (C) Service and entrance courts;
- (D) Parking; and
- (E) Orientation;

(5) Simple horizontal and vertical space diagrams that indicate the relationship of various departments and services to each other the general room arrangement in each department; and

(6) A narrative description of proposed mechanical, electrical, and fire protection systems.

(k) **Final construction documents.**

(1) Construction documents shall be prepared by an architect and/or professional engineer licensed by the State of Arkansas.

(2)(A) Architectural construction documents shall be prepared by an architect and engineering construction documents (structural, mechanical, electrical, and civil) shall be prepared by a qualified engineer.

(B) The documents shall be stamped with appropriate seals for each discipline.

(3)(A) Periodic observations of construction shall be provided and documented by each design professional.

(B) Design professionals shall verify that the:

(i) Construction is in accordance with the construction documents;

and

(ii) Record drawings are properly maintained.

(4) The construction contract shall contain a provision to withhold progress payments to the contractor until the record drawings are current.

(5)(A) Final construction documents shall include drawings and specifications.

(B) Separate drawings and specifications shall be prepared for each of the following branches of work:

(i) Architectural;

(ii) Structural;

(iii) Mechanical;

(iv) Electrical;

(v) Life safety; and

(vi) Fire protection.

(6)(A) The drawings shall include the following information.

(B) **Architectural.**

(i)(a) Approved plan showing all the:

(1) New topography;

(2) Newly established levels and grades;

(3) Existing structures on the site, if any;

(4) New buildings and structures;

(5) Roadways;

(6) Walks;
(7) Extent of the areas to be planted; and
(8) Structures and improvements removed under the construction contract.

(b) A print of the survey included with the working drawings.
(ii) Plan of each floor, roof, and all intermediate levels.
(iii) Elevations of each exterior wall.
(iv) Sections through building.
(v) Scale details as necessary to properly indicate portions of the work.

(vi) Schedule of finishes.

(C) Equipment.

(i) Large-scale drawings of typical and special rooms indicating all:
(a) Fixed equipment; and
(b) Major items of furniture and movable equipment.
(ii) The furniture and movable equipment not included in the construction contract shall be indicated by dotted lines.

(D) Structural.

(i) Plans of foundations, floors, roofs, and all intermediate levels shall show a:
(a) Complete design with sizes, sections, and the relative location of the various members; and
(b) Schedule of:
(1) Beams;
(2) Girders; and
(3) Columns.
(ii) Dimensional floor levels, column centers, and offsets.
(iii) Special openings.
(iv) Details of all:
(a) Special connections;

(b) Assemblies; and

(c) Expansion joints.

(v) Name of the governing building code.

(E) **Mechanical.**

(i) Heating, piping, and air conditioning systems:

(a) Steam-heated equipment, such as:

(1) Sterilizers;

(2) Warmers; and

(3) Steam tables;

(b) Heating and steam mains and branches with pipe sizes;

(c) Diagram of heating and steam risers with pipe sizes;

(d) Sizes, types, and heating surfaces of boilers and oil burners,

if any;

(e) Pumps, tanks, boiler breeching and piping, and boiler room

accessories;

(f) Air conditioning systems with:

(1) Required equipment;

(2) Water refrigerant piping; and

(3) Ductwork showing required fire smoke/dampers;

(g) Air quantities for all room supply, return, and exhaust

ventilating duct openings;

(h) A ventilation schedule specifying the following information:

(1) Room number;

(2) Room name;

(3) Room volume in cubic feet (ft³);

(4) Required room air changes;

(5) Required outside air changes;

(6) Required air movement relative to adjacent area;

(7) Required air filtration in percent (%) efficiency;

(8) Required room total supply air quantity (CFM);

- (9) Required room exhaust air quantity (CFM);
- (10) Design room total supply air quantity (CFM);
- (11) Design room return air quantity (CFM);
- (12) Design outside air quantity (CFM);
- (13) Design room exhaust air quantity (CFM);
- (14) Design room air filtration in percent (%) efficiency;
- (15) Room design summer (°F), dry bulb/wet bulb (DB/WB);
- (16) Room design winter (°F) DB/WB;
- (17) Outside air design summer (°F) DB/WB; and
- (18) Outside air design winter (°F) DB/WB; and
- (i) Air filter design pressure drop, both clean and dirty.
- (ii) Plumbing, drainage, and standpipe systems:
 - (a) Size and elevation of:
 - (1) Street sewer;
 - (2) House sewer;
 - (3) House drains; and
 - (4) Street water main;
 - (b) Locations and size of soil, waste, and vent stacks with connections to:
 - (1) House drains;
 - (2) Clean outs;
 - (3) Fixtures; and
 - (4) Equipment;
 - (c) Size and location of hot and cold circulating mains, branches, and risers from the service entrance and tanks;
 - (d) Riser diagram to show all plumbing stacks with:
 - (1) Vents;
 - (2) Water risers; and
 - (3) Fixture connections;
 - (e) Gas, oxygen, and special connections;

(f) Standpipe and sprinkler systems; and
(g) Plumbing fixtures and equipment that require water and drain connections.

(iii) **Elevators and dumbwaiters.** Details and dimensions of shaft, pit, and machine room, pit sumps with alarms when required, and sizes of car platform and doors.

(iv) Kitchens, laundry, refrigeration, and laboratories detailed at a satisfactory scale (one-quarter-inch scale) to show the location, size, and connection of all fixed and moveable equipment.

(F) **Electrical.**

(i) All electrical wiring, outlets, smoke detectors, and equipment that require electrical connections.

(ii) Electrical service entrance with switches and feeders to the public service feeders, characteristics of the light and power current and transformers and their connections, if located in the building.

(iii)(a) Plan and diagram showing:

(1) Main switchboard power panels;

(2) Light panels; and

(3) Equipment.

(b) Diagram of feeder and conduit sizes with a schedule of feeder breakers or switches.

(iv) Light outlets, receptacles, switches, power outlets, and circuits.

(v) Telephone layout showing:

(a) Service entrance;

(b) Telephone switchboard;

(c) Terminal boxes; and

(d) Telephone outlets.

(vi) Nurse call systems with outlets for beds, nurses' stations, door signal lights, annunciators, and wiring diagrams.

(vii) Staff paging and doctor's in-and-out registry systems with all equipment wiring, if provided.

(viii) Fire alarm and/or security system with:

- (a) Stations;
- (b) Signal devices;
- (c) Control board; and
- (d) Wiring diagrams.

(ix) Emergency electrical system with:

- (a) Outlets;
- (b) Transfer switch;
- (c) Source of supply;
- (d) Feeders; and
- (e) Circuits.

(x) Medical gas alarm systems.

(xi) All other electrically operated systems and equipment.

(G) Life safety and fire protection.

(i) Limits of each smoke compartment.

(ii) Location of each smoke barrier wall.

(iii) Dimensions and gross areas of each smoke compartment.

(iv) Location of each:

- (a) Fire-rated wall or partition;
- (b) Fire separation wall; and
- (c) Horizontal exit.

(v) Location of each:

- (a) Exit sign;
- (b) Fire pull station;
- (c) Extinguisher cabinet; and
- (d) Extinguisher.

(vi) Travel distance or distances from the most remote location or locations in the building to an exit as defined by NFPA 101 (i.e., horizontal exit, exit passageway, enclosed exit stair, exterior exit door).

(H) **Specifications.** Specifications shall:

(i) Supplement the drawings to fully describe:

(a) Types;

(b) Sizes;

(c) Capacities;

(d) Workmanships;

(e) Finishes; and

(f) Other characteristics of all materials and equipment; and

(ii) Include the following:

(a) Cover or title sheet with architectural seal;

(b) Index;

(c) General conditions;

(d) General requirements; and

(e) Sections describing material and workmanship in detail for

each class of work.

(I)(i) All construction documents and specifications shall be approved by the Department of Health prior to the beginning of construction and a letter shall be issued from the licensing agency granting approval to commence with construction.

(ii) The Department of Health shall have a minimum of six (6) weeks to review construction documents and specifications.

(iii) The Division of Health Facilities Services shall coordinate the plan review with other divisions in the Department of Health.

(iv) For penalties for starting construction without Department of Health approval, see 20 CAR § 43-103(m), licensure and codes.

(I) **Site inspection during construction.** The Department of Health shall inspect the project during the construction process as indicated below:

(1) The Department of Health is to be notified when construction begins and a construction schedule shall be submitted to determine inspection dates;

(2) Representatives from the Department of Health shall have access to the construction premises and the construction project for purposes of making whatever inspections deemed necessary throughout the course of construction; and

(3) Any deviation from the accepted construction documents shall not be permitted during construction until the written request for change or changes in the construction is approved by the Department of Health.

(m) Final site inspection.

(1) Upon completion of construction and prior to the approval by the Department of Health to occupy and use the facility, the owner shall be furnished a complete set of recorded drawings and a complete set of installation, operation, and maintenance manuals and parts lists for the installed equipment.

(2) A list of final site inspection items has been provided in Table 5 of Appendix A.

(3) No facility shall occupy any new structure or major addition or renovation space until the appropriate permission has been received from the:

(A) Local building and fire authorities; and

(B) Licensing agency.

(n) Referenced publications.

(1) General.

(A) This part includes references to other codes and standards.

(B) The most current codes and standards adopted at the time of this publication are used.

(C)(i) Later issues will normally be acceptable where requirements for function and safety are not reduced.

(ii) However, editions of different dates may have portions renumbered or retitled.

(D) Care shall be taken to ensure that appropriate sections are used.

(2) Publications adopted in whole by this part are as listed below:

(A) American National Standards Institute (ANSI) Standard A17.1, Safety Code for Elevators and Escalators;

(B) American Society of Civil Engineers (ASCE), Minimum Design Loads for Buildings and Other Structures;

(C) Title 22, Subchapter B, Building Authority Minimum Standards and Criteria, Part 111, Design Review Section, Accessibility for Individuals with Disabilities Standards, 22 CAR § 111-1001 et seq.;

(D) National Council on Radiation Protection and Measurements (NCRP), Report No. 33, Medical X-ray and Gamma Ray Protection for Energies Up to 10 MeV — Equipment Design and Use, 1986;

(E) National Council on Radiation Protection and Measurements (NCRP), Report No. 49, Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to 10 MeV, 1976;

(F) National Council on Radiation Protection and Measurements (NCRP), Radiation Protection Design Guidelines for 0.1 to 100 MeV Particle Accelerator Facilities;

(G)(i) National Fire Protection Association 101, Life Safety Code, 2000 Edition.

(ii) Note that “mandatory references” are listed in chapter two (2) of this document; and

(H) The Department of Health’s Rules Pertaining to the Management of Medical Waste from Generators and Health Care Related Facilities, 20 CAR pt. 53.

(3) Publications adopted in part (only the sections specifically identified by this part are applicable) by this part are as listed below:

(A) American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), ASHRAE Handbook — Fundamentals and ASHRAE Handbook — HVAC Applications;

(B) American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), Standard 52, Method of Testing Air Cleaning Devices Used in General Ventilation for Removing Particulate Matter; and

(C) Illuminating Engineering Society, IESNA Publication CP29, Lighting for Health Care Facilities.

(4) A partial list of other publications that are applicable to the design and construction of healthcare facilities that are not a part of this part but may be enforced by other authorities having jurisdiction is provided below:

(A) Arkansas Fire Prevention Code Volumes I, II, and III, based on the 2000 International Building Code;

(B) Mechanical Code, 17 CAR pt. 260, Department of Health;

(C) Arkansas Plumbing Code, 17 CAR pt. 65, Department of Health; and

(D) Administrative Rules of the Boiler Inspection Division, 20 CAR pt. 880.

(5) Publications that are not a part of this part but potentially helpful as reference material in the design and construction of healthcare facilities are as listed below:

(A) American Institute of Architects (AIA), Guidelines for Design and Construction of Hospital and Health Care Facilities, 2001 Edition; and

(B) American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE), HVAC Design Manual for Hospitals and Clinics.

(o) Availability of codes and standards.

(1) Referenced publications can be ordered, if they are government publications, from the Superintendent of Documents, Government Publishing Office , 732 North Capitol St NW, Washington, DC, 20001.

(2)(A) Copies of nongovernment publications can be obtained at the addresses listed below.

(B) Air-Conditioning, Heating, and Refrigeration Institute, 2311 Wilson Boulevard, Suite 400, Arlington, VA, 22201.

(C) American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY, 10036.

(D) Metropolitan Section, American Society of Civil Engineers, 32 Nassau St. #60537, New York, NY, 10038.

(E) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA, 19428.

(F) American Society of Heating, Refrigerating, and Air-Conditioning Engineers, 180 Technology Parkway NW, Peachtree Corners, GA, 30092.

(G) Building Authority Division, 501 Woodlane, Suite 101N, Little Rock, AR, 72201.

(H) Division of Labor, 900 West Capitol Avenue, Suite 400, Little Rock, AR, 72201.

(I) Illuminating Engineering Society (IES), 120 Wall Street, 17th Floor, New York, NY, 10005.

(J) National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 400, Bethesda, MD, 20814.

(K) National Fire Protection Association, 1 Batterymarch Park, Post Office Box 9101, Quincy, MA, 02169.

(L) International Code Council, 900 Montclair Road, Birmingham, AL, 35213.

(p) Interpretations of requirements.

(1) **Memorandum of understanding.** Conflicts between the Arkansas Fire Prevention Code and NFPA 101: Life Safety Code are to be resolved using the memorandum of understanding as indicated below:

(A) The Arkansas Fire Prevention Code is the fire prevention code for the State of Arkansas;

(B) When the Arkansas Fire Prevention Code conflicts with the chapters of NFPA 101: Life Safety Code governing new and existing healthcare and ambulatory healthcare occupancies (chapters 18, 19, 20, and 21), the provisions of the Life Safety Code shall govern; and

(C)(i) Requirements found only in the Arkansas Fire Prevention Code, requirements not addressed by NFPA 101, may be provided at the option of the facility.

(ii) Compliance with these requirements is not mandatory.

(2) Safety improvement plans.

(A) Nothing in this part shall be construed as restrictive to a facility that chooses to do work as a part of a long-range safety improvement plan.

(B) This part does not prohibit a single phase of improvement.

(C) All hazards to life and safety and all areas of noncompliance should be corrected as soon as possible.

(3) **Provisions in excess of regulatory requirements.** Nothing in this part shall be construed to prohibit a better type of building construction, an additional means of egress, or an otherwise safer condition than that specified by the minimum requirements of this part.

(4) **Equivalency.**

(A)(i) Insofar as practical, these minimum standards have been established to obtain a desired performance result.

(ii) Prescriptive limitations when given, such as exact minimum dimensions or quantities, describe a condition that is recognized as a practical standard for normal operation.

(B)(i) It is the intent of this part to permit and promote equivalency concepts.

(ii) Nothing in this part shall be construed as restricting innovations that provide an equivalent level of performance with this part in a manner other than that which is prescribed by this part provided that no other safety element or system is compromised in order to establish equivalency.

(C) The Division of Health Facilities Services may approve alternate methods, procedures, design criteria, and functional variations from this part because of extraordinary circumstances, new programs, new technology, or unusual conditions when the facility can effectively demonstrate that the:

(i) Intent of the rules is met; and

(ii) Variation does not reduce the safety or operational effectiveness of the facility below that required by the exact language of the rules.

(D)(i) When contemplating equivalency allowances, the Division of Health Facilities Services may use a variety of expert sources to make equivalency findings.

(ii) The Division of Health Facilities Services will document the reasons for approval or denial of equivalency to the facility.

(E)(i) The National Fire Protection Association (NFPA) document 101A is a technical standard for evaluating equivalency to certain Life Safety Code 101 requirements.

(ii) The Fire Safety Evaluation System (FSES) is a widely recognized method for establishing a safety level equivalent to the Life Safety Code.

(iii) The use of the FSES process may be useful for evaluating existing facilities that will be affected by renovation.

20 CAR § 43-143. Physical facilities — Patient accommodations — Adult medical, surgical — Communicable or pulmonary disease.

(a) **Note.** See other sections of this document for special care area units such as:

- (1) Postanesthesia care units;
- (2) Critical care units;
- (3) Rehabilitation units;
- (4) Pediatric units;
- (5) Postpartum care units; and/or
- (6) Other specialty units.

(b) **Patient rooms.** Each patient room shall meet the following requirements:

- (1) Maximum room capacity shall be two (2) patients;
- (2)(A) In new construction, patient rooms shall have a minimum of one hundred square feet (100 sq. ft.) of clear floor area per bed in semiprivate rooms and one hundred twenty square feet (120 sq. ft.) of clear floor area for single-bed rooms, exclusive of:

- (i) Toilet rooms;
- (ii) Closets;
- (iii) Lockers;
- (iv) Wardrobes;
- (v) Alcoves; or

(vi) Vestibules.

(B) The dimensions and arrangement of rooms shall be such that there is a minimum of three feet (3') between the sides and foot of the bed and:

(i) Any wall or other fixed obstruction; or

(ii) Another bed.

(C) In semiprivate bedrooms, a clearance of four feet (4') shall be available at the foot of each bed to permit the passage of equipment and beds.

(D) Minor encroachments, including columns and lavatories, that do not interfere with functions may be ignored when determining space requirements for patient rooms.

(E) Where renovation work is undertaken, every effort shall be made to meet the above minimum standards;

(3)(A) Each patient room shall have a window with outside exposure and where the operation of windows or vents requires the use of tools or keys, such devices shall be:

(i) On the same floor; and

(ii) Easily accessible to staff;

(B) The windowsills shall:

(i) Not be higher than three feet (3') above the floor; and

(ii) Be above the grade;

(C) Patient rooms in new construction intended for twenty-four-hour occupancy shall have windows.

(D) If operable windows are installed, such devices shall be permanently secured or restricted to inhibit possible escape or suicide;

(4) Nurse patient communication stations shall be provided in accordance with 20 CAR § 43-171(g), physical environment — electrical standards;

(5)(A) Handwashing stations shall be provided to serve each patient room.

(B) These handwashing stations shall be located in the toilet room;

(6)(A) Each patient shall have access to a toilet room without having to enter the general corridor area.

(B) One (1) toilet room shall serve no more than:

- (i) Four (4) patient beds; and
- (ii) Two (2) patient rooms.

(C) In new construction, an additional handwashing station or sanitizing station shall be placed in the patient room where the toilet room serves more than one (1) bed.

(D) The toilet room shall contain a water closet and a handwashing station and the door shall swing outward or be double-acting;

(7) Each patient shall have within the room a separate wardrobe or closet that is suitable for:

- (A) Hanging full-length garments; and
- (B) Storing personal items;

(8)(A) Visual privacy from casual observation by other patients and visitors shall be provided for each patient in semiprivate rooms with:

- (i) Cubicle curtains; or
- (ii) Equivalent built-in or movable dividers.

(B) Provisions for privacy are not required within psychiatric or alcohol and drug units.

(C) The method for providing privacy shall not obstruct passage of other patients to the:

- (i) Entrance;
- (ii) Toilet; or
- (iii) Lavatory.

(D) All curtains shall:

- (i) Have a flame spread of 0 to 25; and
- (ii) Comply with NFPA 13 requirements for clear space below

sprinklers;

(9) Each room shall communicate directly with a corridor without passage through another patient's room;

(10) Rooms existing partially below grade level shall not be used for patients unless they are:

- (A) Dry;
- (B) Well-ventilated; and
- (C) Otherwise suitable for occupancy;

(11) Beds shall be arranged to:

- (A) Provide adequate room for all patient care procedures; and
- (B) Prevent the transmission of infections;

(12)(A) Individual approved hospital-type beds shall be provided.

- (B) Bed rails shall be provided on beds for children;

(13)(A) A reading light shall be provided for each patient bed.

(B) The location and design shall be such that the light is not annoying to other patients; and

(14)(A) A bedside table with drawer shall be provided for each bed.

(B) The lower portion of the table and/or enclosed shelves shall be provided for individual nursing care equipment.

(c) Service areas.

(1) Each service area may be arranged and located to serve more than one (1) nursing unit but at least one (1) such service area shall be provided on each nursing floor.

(2) Some of the service areas may be combined in a single space.

(3) The following service areas shall be located in or readily available to each nursing unit:

(A)(i) Nursing station.

(ii) Facilities for charting, clinical records, work counter, communication system, space for supplies, and convenient access to handwashing stations shall be provided.

(iii) It may be combined with or include centers for reception and communication;

(B)(i) Dictation area shall be provided.

(ii) This area shall be adjacent to but separate from the nurses' station;

(C)(i) Toilet room or rooms for staff convenient to nurses' station.

(ii) May be unisex;

(D)(i) Lounge facilities for staff.

(ii) These facilities may be on another floor;

(E)(i) Individual closets or compartments for the safekeeping of coats and personal effects of nursing personnel.

(ii) These shall be located:

(a) Convenient to the nurses' station of personnel; or

(b) In a central location;

(F)(i) Multipurpose room or rooms for staff, patients, and patients' families

for:

(a) Patient conferences;

(b) Reports;

(c) Education;

(d) Training sessions; and

(e) Consultation.

(ii) The rooms shall be accessible to each nursing unit.

(iii) One (1) such room may serve several nursing units and/or

departments;

(G)(i) Examination/treatment room or rooms.

(ii) Such rooms may be omitted if all patient rooms are single-bed rooms.

(iii) It shall have a minimum floor area of one hundred twenty square feet (120 sq. ft.) excluding space for vestibule, toilet, closets, and work counters, whether fixed or movable.

(iv) Centrally located examination and treatment room or rooms may serve more than one (1) nursing unit on the same floor.

(v) The room shall contain:

- (a) A lavatory or sink equipped for handwashing;
- (b) A work counter;
- (c) Storage facilities; and
- (d) A desk, counter, or shelf space for writing.

(vi) The emergency treatment room may be used for this purpose if it is conveniently located to the patient rooms;

(H)(i) Clean workroom or clean supply room.

(ii) If the room is used for preparing patient care items, it shall contain:

- (a) A work counter;
- (b) A handwashing fixture; and
- (c) Storage facilities for clean and sterile supplies.

(iii) If the room is used only for storage and holding as part of a system for distribution of clean and sterile materials, the work counter and handwashing fixture may be omitted.

(iv) Soiled and clean workrooms or holding rooms shall:

- (a) Be separated; and
- (b) Have no direct connection;

(I)(i) Soiled workroom or soiled holding room.

(ii) This room shall be separate from the clean workroom.

(iii) The soiled workroom shall contain a clinical sink or equivalent flushing-rim fixture.

(iv) The room shall contain a lavatory or handwashing fixture.

(v) The above fixtures shall both have a hot and cold mixing faucet.

(vi) The room shall have:

- (a) A work counter; and
- (b) Space for separate covered containers for soiled linen and

waste.

(vii) Rooms used only for temporary holding of soiled material may omit the clinical sink and work counter.

(viii) If the flushing-rim clinical sink is eliminated, facilities for cleaning bedpans shall be provided elsewhere;

(J)(i) Medication station.

(ii) Provisions shall be made for distribution of medications.

(iii) This may be done:

(a) From a medicine preparation room or unit;

(b) From a self-contained medicine dispensing unit; or

(c) By another approved system.

(iv) **Medicine preparation room.**

(a) This room shall be designed to allow for visual supervision by the nursing staff.

(b) It shall contain:

(1) A work counter;

(2) A sink adequate for handwashing;

(3) A refrigerator; and

(4) Locked storage for controlled drugs.

(c) When a medicine preparation room is to be used to store one (1) or more self-contained medicine dispensing units, the room shall be designed with adequate space to prepare medicines with the self-contained medicine dispensing unit or units present.

(v) **Self-contained medicine dispensing unit.**

(a) A self-contained medicine dispensing unit may be located at the nurses' station, in the clean workroom, or in an alcove, provided the unit has adequate:

(1) Security for controlled drugs; and

(2) Adequate lighting to easily identify drugs.

(b) Convenient access to handwashing stations shall be provided.

(c) Standard cup-sinks provided in many self-contained units are not adequate for handwashing;

(K)(i) Clean linen storage.

(ii) A separate closet or a designated area within the clean workroom shall be provided.

(iii) If a closed cart system is used, storage may be in an alcove.

(iv) Carts shall be out of the path of traffic;

(L)(i) Nourishment station.

(ii) This shall contain:

(a) A sink equipped for handwashing;

(b) Equipment for serving nourishment between scheduled and unscheduled meals;

(c) A refrigerator;

(d) Storage cabinets; and

(e) Ice maker units to provide ice for patients' service and treatment.

(iii) Ice for human consumption shall be from self-dispensing units.

(iv) Handwashing stations shall be in or immediately accessible to the nourishment station;

(M)(i) Equipment storage room.

(ii) This shall be for equipment such as:

(a) IV stands;

(b) Inhalators;

(c) Air mattresses; and

(d) Walkers;

(N)(i) Parking for stretchers and wheelchairs.

(ii) This shall be located out of the path of normal traffic;

(O)(i) Showers and bathtubs.

(ii) When individual bathing facilities are not provided in patient rooms, there shall be at least one (1) shower and/or bathtub for every twelve (12) beds without such facilities.

(iii) Each bathtub or shower shall be in an Individual room or enclosure that provides privacy for:

- (a) Bathing;
- (b) Drying; and
- (c) Dressing.

(iv) Special bathing facilities including space for attendant shall be provided for patients on stretchers, carts, and wheelchairs at the ratio of:

- (a) One (1) per one hundred (100) beds; or
- (b) A fraction thereof.

(v) This may be on a separate floor if convenient for use;

(P)(i) Emergency equipment storage.

(ii) Space for emergency equipment such as a "crash cart" shall be:

- (a) Provided; and
- (b) Under control of the nursing staff; and

(Q)(i) Environmental services closet.

(ii) See 20 CAR § 43-164, physical facilities — cleaning and sanitizing carts, employee facilities, and environmental closets, for detailed requirements.

(d) Airborne infection isolation room or rooms.

(1) Rooms for patients who are suffering from infections shall be provided at the rate of one (1) for every thirty (30) beds or fraction thereof.

(2) These may be located:

- (A) Within each nursing unit; or
- (B) Placed together in a separate unit.

(3) See also 20 CAR § 43-131, physical facilities — critical care for the requirements of critical care units.

(4) Psychiatric and alcohol/drug unit or units beds need not be included in the bed count ratio to establish the number of rooms.

(5) Each isolation room shall be a single-bed room and planned as required for a normal patient room except as follows:

(A) Each airborne infection isolation room shall have an anteroom for handwashing, gowning, and storage of clean and soiled materials located directly outside the entry door to the patient room;

(B) Airborne infection isolation room perimeter walls, ceiling, and floors, including penetrations, shall be sealed tightly so that air does not infiltrate the environment from the outside or from other spaces;

(C) Airborne infection isolation room or rooms shall have self-closing devices on all room exit doors;

(D) Separate toilet, bathtub or shower, and handwashing stations are required for each airborne infection isolation room;

(E) Airborne infection isolation rooms may be used for noninfectious patients when not needed for patients with airborne infectious disease;

(F) Windows shall not be operable without the use of a key or tool controlled by the nursing staff; and

(G) Each room shall have a permanently installed visual mechanism to constantly monitor the pressure status of the room when occupied by patients with an airborne infectious disease.

(e) Protective isolation rooms.

(1) In facilities where procedures such as organ transplants, burn therapy, and immunosuppressive treatments are performed, special design provisions including special ventilation may be necessary to meet the needs of the functional program.

(2) Refer to Table 4 of Appendix A for air pressure and ventilation.

(3) Each protective isolation room shall be a single-bed room and planned as required for a normal patient room except as follows:

(A) Each protective isolation room shall have an anteroom for handwashing, gowning, and storage of clean and soiled materials located directly outside the entry door to the patient room;

(B) Protective isolation room perimeter walls, ceiling, and floors, including penetrations, shall be sealed tightly so that air does not infiltrate the environment from the outside or from other spaces;

(C) Protective isolation room or rooms shall have self-closing devices on all room exit doors;

(D) Separate toilet, bathtub or shower, and handwashing stations are required for each protective isolation room;

(E) Protective isolation rooms may be used for nonimmunosuppressed patients, except airborne infectious patients are prohibited; and

(F) Windows shall not be operable without the use of a key or tool controlled by the nursing staff.

(f) Seclusion rooms.

(1) Each hospital shall provide one (1) or more single-bed rooms for patients needing close supervision if suitable psychiatric facilities are not available elsewhere in the community.

(2) Such rooms shall comply with the applicable requirements in 20 CAR § 43-147, physical facilities — psychiatric nursing unit.

(g) Observation rooms. Patients in observation status may be accommodated within the facility:

(1) **In private, semiprivate, or multipatient rooms.** Furniture shall be arranged to:

(A) Provide adequate room for patient care procedures; and

(B) Prevent the transmission of infection;

(2)(A) Cubicle curtains, privacy screens, or an approved equivalent shall be provided for patient privacy in all multipatient rooms.

(B) The utilization of such curtains or screens shall be such that each patient shall have privacy;

(3) Each room or cubicle shall be provided with:

(A) Oxygen;

(B) Vacuum; and

(C) A nurse call button unless direct observation is afforded and maintained;

(4) Hand hygiene facilities shall be available within the area;

(5)(A) Hospital-grade furniture shall be provided.

(B) Bed rails shall be provided on beds;

(6)(A) For each area in which a patient bed is utilized, a reading light shall be provided for each bed.

(B) The location and design shall be such that the light is not annoying to other patients;

(7) Patient toilets shall be provided and accessible to all patients; and

(8) Adequate space shall be provided for medical supplies.

20 CAR § 43-144. Physical facilities — Critical care unit.

(a)(1) The critical care units require special space and equipment considerations for effective staff functions.

(2) In addition, space arrangement shall include provisions for immediate access of emergency equipment from other departments.

(3) Critical care units shall comply in size, number, and type with:

(A) These standards; and

(B) The functional program.

(4) The following standards are intended for the more common types of critical care services and shall be appropriate to needs defined in functional programs.

(5) Where specialized services are required, additions and/or modifications shall be made as necessary for efficient, safe, and effective patient care.

(b) Critical care — General.

(1) The following shall apply to all types of critical care units unless otherwise noted.

(2) Each unit shall comply with the following provisions:

(A)(i) The location shall offer direct access by the emergency, respiratory care, laboratory, radiology, surgery, and other essential departments and services as defined by the functional program.

(ii) It shall be located so that the medical emergency resuscitation teams may be able to respond promptly to emergency calls within minimum travel time.

(iii) The location shall be arranged to eliminate the need for through traffic;

(B) In new construction, where elevator transport is required for critically ill patients, the size of the cab and mechanisms and controls shall meet the specialized needs;

(C)(i) In new construction, each patient room, or multiple bed space for neonatal or pediatric units, shall have a minimum of two hundred square feet (200 sq. ft.) of clear floor area with a minimum headwall width of thirteen feet (13') per bed exclusive of:

- (a)* Anterooms;
- (b)* Vestibules;
- (c)* Toilet rooms;
- (d)* Closets;
- (e)* Lockers;
- (f)* Wardrobes; and/or
- (g)* Alcoves.

(ii) In renovation of existing critical care units, every effort shall be made to meet the above minimum standards.

(iii)(a) If it is not possible to meet the above square-foot standards, the entity having jurisdiction may grant approval to deviate from this requirement.

(b) In such cases, rooms shall be no less than one hundred thirty square feet (130 sq. ft.);

(D)(i) View panels to the corridor shall:

- (a)* Be required; and
- (b)* Have means to provide visual privacy.

(ii) Where only one (1) door is provided to a bed space, it shall be:

- (a)* At least four feet (4') wide; and
- (b)* Arranged to minimize interference with movement of beds

and large equipment.

(iii) Sliding doors shall:

- (a)* Not have floor tracks; and
- (b)* Have hardware that minimizes jamming possibilities.

(iv) Where sliding doors are used for access to cubicles within a suite, a three-foot-wide swinging door may also be provided for personnel communication.

(v) The sliding doors shall swing out;

(E)(i) Each patient bed area shall have:

(a) Space at each bedside for visitors; and

(b) Provisions for visual privacy from casual observation by other patients and visitors.

(ii) For both adult and pediatric units, there shall be a minimum of eight feet (8') between beds;

(F)(i) Each patient bed shall have visual access other than skylights to the outside environment with not less than one (1) outside window in each patient bed area.

(ii) In renovation projects, clerestory windows with windowsills above the heights of adjacent ceilings may be used provided they:

(a) Afford patients a view of the exterior; and

(b) Are equipped with appropriate forms of glare and sun control.

(iii) Distance from the patient bed to the outside window shall not exceed fifty feet (50').

(iv) When partitioned cubicles are used, patients' view to outside windows may be through no more than two (2) separate clear vision panels;

(G)(i) Nurse/patient communication shall be provided in accordance with 20 CAR § 43-171(g), physical environment — electrical standards.

(ii) The communication station for the unit shall include provisions for an emergency code resuscitation alarm to summon assistance from outside the critical care unit;

(H)(i) Handwashing fixtures shall be convenient to nurses' stations and patient bed areas.

(ii) There shall be at least:

(a) One (1) handwashing fixture for every three (3) beds in open plan areas; and

- (b) One (1) in each patient room.
- (iii) The handwashing fixture or sanitizing station shall be:
 - (a) Located near the entrance to the patient cubicle or room;
 - (b) Sized to minimize splashing water onto the floor; and
 - (c) Equipped with hands-free operable controls;
- (I)(i) Nurses' station shall have space for counters and storage.
- (ii) It may be combined with or include centers for reception and communication.
 - (iii) There shall be direct or remote visual observation between:
 - (a) The nurses' station; and
 - (b) All patient beds in the critical care unit;
- (J)(i) Each unit shall contain equipment for continuous monitoring with visual displays for each patient at the bedside and at the nurses' station.
 - (ii) Monitors shall be located to permit easy viewing and access but not interfere with access to the patient;
- (K) Emergency equipment storage space that is easily accessible to the staff shall be provided for emergency equipment such as an emergency cart;
- (L)(i) Medication station.
 - (ii) Provisions shall be made for distribution of medications.
 - (iii) This may be done:
 - (a) From a medicine preparation room or unit;
 - (b) From a self-contained medicine dispensing unit; or
 - (c) By another approved system.
 - (iv) **Medicine preparation room.**
 - (a) This room shall be designed to allow for visual supervision by the nursing staff.
 - (b) It shall contain:
 - (1) A work counter;
 - (2) A sink adequate for handwashing;
 - (3) A refrigerator; and

(4) Locked storage for controlled drugs.

(c) When a medicine preparation room is to be used to store one (1) or more self-contained medicine dispensing units, the room shall be designed with adequate space to prepare medicines with the self-contained medicine dispensing unit or units present.

(v) **Self-contained medicine dispensing unit.**

(a) A self-contained medicine dispensing unit may be located at the nurses' station, in the clean workroom, or in an alcove provided the unit has adequate:

(1) Security for controlled drugs; and

(2) Lighting to easily identify drugs.

(b) Convenient access to handwashing stations shall be provided.

(c) Standard cup-sinks provided in many self-contained units are not adequate for handwashing;

(M)(i) At least one (1) airborne infection isolation room with anteroom shall be provided.

(ii) The number of airborne infection isolation rooms shall be determined based on an infection control risk assessment per the primary catchment area by the facility.

(iii) Each room shall:

(a) Contain only one (1) bed; and

(b) Comply with the requirements of 20 CAR § 43-143(d), physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease.

(iv) However, the requirement for the bathtub or shower may be eliminated.

(v) Compact, modular toilet/sink combination units may replace the requirement for a toilet room.

(vi) Special ventilation requirements are found in Table 4 of Appendix

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(N)(i) The following additional service spaces shall be immediately available within each critical care area.

(ii) **Note.** These additional spaces may be shared by more than one (1) critical care unit provided that direct access is available from each unit:

(a) Securable closets or cabinet compartments for the unit personnel;

(b)(1) Clean workroom or clean supply room.

(2) If the room is used for preparing patient care items, it shall contain:

(A) A work counter;

(B) A handwashing fixture; and

(C) Storage facilities for clean and sterile supplies.

(3) If the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixture may be omitted.

(4) Soiled and clean workrooms or holding rooms shall:

(A) Be separated; and

(B) Have no direct connection;

(c) Clean linen storage.

(1) There shall be a designated area for clean linen storage.

(2) This may be within:

(A) The clean workroom;

(B) A separate closet; or

(C) An approved distribution system on each floor.

(3) If a closed cart system is used, storage may be in an alcove.

(4) It shall be:

(A) Out of the path of normal traffic; and

(B) Under staff control;

(d)(1) Soiled workroom or soiled holding room.

- (2) This room shall be separate from the clean workroom.
- (3) The soiled workroom shall contain:
- (A) A clinical sink; or
 - (B) Equivalent flushing-rim fixture.
- (4) The room shall contain a lavatory or handwashing fixture.
- (5) The above fixtures shall have a hot and cold mixing faucet.
- (6) The room shall have:
- (A) A work counter; and
 - (B) Space for separate covered containers for:
 - (i) Soiled linen; and
 - (ii) A variety of waste types.
- (7) Rooms used only for temporary holding of soiled material may omit the clinical sink and work counter.
- (8) If the flushing-rim clinical sink is eliminated, facilities for cleaning bedpans shall be provided elsewhere;
- (e)(1) Nourishment station.
- (2) There shall be a nourishment station with:
- (A) Sink;
 - (B) Work counter;
 - (C) Refrigerator;
 - (D) Storage cabinets; and
 - (E) Equipment for hot and cold nourishments between scheduled meals.
- (3) The nourishment station shall include space for trays and dishes used for nonscheduled meal service.
- (4) Provisions and space shall be included for separate temporary storage of unused and soiled dietary trays not picked up at meal time.

(5) Handwashing stations shall be in or immediately accessible from the nourishment station;

(f)(1) Ice machine.

(2) There shall be available equipment to provide ice for treatments and nourishment.

(3) Icemaking equipment may be:

(A) In the clean work room; or

(B) At the nourishment station.

(4) Ice intended for human consumption shall be from self-dispensing ice makers;

(g)(1) Equipment storage room or alcove.

(2) Appropriate room or rooms or alcove or alcoves shall be provided for storage of large items of equipment:

(A) Necessary for patient care; and

(B) As required by the functional program.

(3) Its location shall not interfere with the flow of traffic; and

(h) X-ray viewing equipment; and

(O) The following shall be provided and may be located outside the unit if conveniently accessible:

(i)(a) A visitors' waiting room shall be provided with access to telephones and toilets.

(b) One (1) waiting room may serve several critical care units;

(ii)(a) Staff lounge or lounges and toilet or toilets shall be located so that staff may be recalled quickly to the patient area in emergencies.

(b) The lounge shall have telephone or intercom and emergency code alarm connections to the critical care unit it serves.

(c) One (1) lounge may serve adjacent critical care areas;

(iii) A special procedures room shall be provided if required by the functional program;

(iv)(a) Multipurpose room or rooms for staff, patients, and patients' families for patient conferences, reports, education, training sessions, and consultation shall be provided.

(b) These rooms shall be accessible to each nursing unit;

(v)(a) A housekeeping room shall be provided within or immediately adjacent to the critical care unit.

(b) It shall not be shared with other nursing units or departments.

(c) It shall contain:

(1) A service sink or floor receptor; and

(2) Provisions for storage of supplies and housekeeping equipment;

(vi) Storage space for stretchers and wheelchairs shall be provided in a strategic location without restricting normal traffic; and

(vii)(a) Laboratory, radiology, respiratory care, and pharmacy services shall be available.

(b) These services may be provided from the central departments or from satellite facilities as required by the functional program.

(c) **Coronary critical care unit.** In addition to the standards set forth in this section, the following standards apply to the coronary critical care unit:

(1) Each coronary patient shall have a separate room for acoustical and visual privacy; and

(2)(A) Each coronary patient shall have access to a toilet in the room.

(B) Portable commodes may be used in lieu of individual toilets, but provisions shall be made for their:

(i) Storage;

(ii) Servicing; and

(iii) Odor control.

(d) **Pediatric critical care.**

(1) If a facility has a specific pediatric critical care unit, the functional program shall include consideration for staffing, isolation, and the safe transportation of critically ill pediatric patients, along with life support and environmental systems, from other areas.

(2) In addition to the standards previously listed for critical care units, each pediatric critical care unit shall include:

(A) Space at each bedside for:

- (i) Family;
- (ii) Visitors; and
- (iii) Nursing staff;

(B) In new construction, each patient space whether separate rooms, cubicles, or multiple bed space shall have a minimum of two hundred square feet (200 sq. ft.) of clear floor area with a minimum headwall width of thirteen feet (13') per bed exclusive of:

- (i) Anterooms;
- (ii) Vestibules;
- (iii) Toilet rooms;
- (iv) Closets;
- (v) Lockers;
- (vi) Wardrobes; and/or
- (vii) Alcoves;

(C) Consultation/demonstration room within or convenient to the pediatric critical care unit for private discussions;

(D)(i) Provisions for formula storage.

(ii) These may be outside the pediatric critical care unit but shall be available for use at all times;

(E) Separate storage cabinets or closets for toys and games for use by the pediatric patients; and

(F) Examination and treatment room or rooms.

(e) **Newborn intensive care units.** Each newborn intensive care unit (NICU) shall include or comply with the following:

(1)(A) The NICU shall have a clearly identified entrance and reception area for families.

(B) The area shall permit visual observation and contact with all traffic entering the unit.

(C) A scrub area shall be provided at each public entrance to the patient care area or areas of the NICU.

(D) All sinks shall be:

(i) Hands-free operable; and

(ii) Large enough to contain splashing;

(2) At least one (1) door, forty-four inches (44") minimum, to each room in the unit to accommodate portable X-ray equipment;

(3) There shall be controlled access systems to the unit from:

(A) The labor and delivery area;

(B) The emergency room; or

(C) Other referral entry points;

(4) When viewing windows are provided, provision shall be made to control casual viewing of infants;

(5) Noise control shall be a design factor;

(6)(A) Provisions shall be made for indirect lighting in all nurseries.

(B) Provisions shall be made for multiple lighting levels;

(7)(A) A central area shall:

(i) Serve as a nurses' station;

(ii) Have space for counters and storage; and

(iii) Have convenient access to handwashing stations.

(B) It may be combined with or include centers for:

(i) Reception and communication; and

(ii) Patient monitoring;

(8)(A) Each patient care space shall contain a minimum of one hundred twenty square feet (120 sq. ft.) per bassinette excluding sinks and aisles.

(B) There shall be an aisle for circulation adjacent to each patient care space with a minimum width of three feet (3');

(9)(A) An airborne infection isolation room is required in at least one (1) level of nursery care.

(B) The room shall be enclosed and separated from the nursery unit with provisions for observation of the infant from adjacent nurseries or control area or areas;

(10) Blood gas lab facilities shall be immediately accessible;

(11) A respiratory care work area and storage room shall be provided;

(12) A consultation/demonstration/breastfeeding room shall be provided convenient to the unit;

(13) Charting and dictation space for physicians shall be provided;

(14) Medication station shall be provided;

(15)(A) Clean workroom or clean supply room shall be provided.

(B) See 20 CAR § 43-143(c)(3)(H), physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease;

(16)(A) Soiled workroom or soiled holding room shall be provided.

(B) See 20 CAR § 43-143(c)(3)(I), physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease;

(17) A lounge, locker room, and staff toilet within or adjacent to the unit suite for staff use shall be provided;

(18)(A) Space shall be provided for emergency equipment that is under direct control of the nursing staff, such as an emergency cart.

(B) This space shall be located in an area appropriate to the functional program but out of normal traffic;

(19)(A) One (1) environmental services closet shall be provided for the unit.

(B) It shall be:

(i) Directly accessible from the unit; and

(ii) Dedicated for the exclusive use of the neonatal critical care unit.

(C) It shall contain:

- (i) A service sink or floor receptor; and
- (ii) Provisions for storage of supplies and housekeeping equipment;

and

(20) Space shall be provided for the following:

- (A) A visitors' waiting room;
- (B) Nurses' station; and
- (C)(i) Multipurpose room or rooms for staff, patients, and patients'

families for:

- (a)* Patient conferences;
- (b)* Reports;
- (c)* Education;
- (d)* Training sessions; and
- (e)* Consultation.

(ii) These rooms shall be accessible to each nursing unit.

(iii) They may be on other floors if convenient for regular use.

(iv) One (1) such room may serve several nursing units and/or

departments.

20 CAR § 43-145. Physical facilities — Nursery units.

(a)(1) Normal newborn infants shall be housed in nurseries that comply with the standards below.

(2) All nurseries other than pediatric nurseries shall be convenient to the:

- (A) Postpartum nursing unit; and
- (B) Obstetrical facilities.

(3) The nurseries shall be located and arranged to preclude the need for nonrelated pedestrian traffic.

(4) No nursery shall open directly into another nursery.

(5) There should be one (1) breastfeeding/pumping room readily available for mothers of NICU babies to pump breastmilk.

(b) **General.** Each nursery shall contain the following:

(1) At least one (1) lavatory, equipped with hands-free handwashing station, for every eight (8) infant stations;

(2) Glazed observation windows to permit the viewing of infants from:

(A) Public areas;

(B) Workrooms; and

(C) Adjacent nurseries;

(3) Convenient, accessible storage for linens and infant supplies at each nursery room;

(4)(A) A consultation/demonstration/breastfeeding or pump room shall be provided convenient to the nursery.

(B) Provision shall be made, either within the room or conveniently located nearby, for:

(i) Sink;

(ii) Counter;

(iii) Refrigeration and freezing;

(iv) Storage for pump and attachments; and

(v) Educational materials.

(C) The area provided for the unit for these purposes, when conveniently located, may be shared;

(5) Enough space shall be provided for parents to stay twenty-four (24) hours;

(6)(A) An airborne infection isolation room is required in or near at least one (1) level of nursery care.

(B) The room shall be enclosed and separated from the nursery unit with provisions for observation of the infant from adjacent nurseries or control area or areas.

(C) All airborne infection isolation rooms shall comply with the requirements of 20 CAR § 43-143(d), physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease except for separate:

(i) Toilet;

(ii) Bathtub; or

(iii) Shower;

(7)(A) Workroom or workrooms.

(B) Each nursery room shall be served by a connecting workroom.

(C) The workroom shall contain:

(i) Scrubbing and gowning facilities at the entrance for staff and housekeeping personnel;

(ii) Work counter;

(iii) Refrigerator;

(iv) Storage for supplies; and

(v) A hands-free handwashing fixture.

(D) One (1) workroom may serve more than one (1) nursery room provided that required services are convenient to each.

(E) The workroom serving the full-term and continuing care nurseries may be omitted if equivalent work and storage areas and facilities, including those for scrubbing and gowning, are provided within that nursery.

(F) Space required for work areas located within the nursery is in addition to the area required for infant care.

(G)(i) Adequate provision shall be made for:

(a) Storage of emergency cart or carts and equipment out of traffic; and

(b) The sanitary storage and disposal of soiled waste.

(ii) When the functional program includes a mother-baby couplet approach to nursing care, the workroom functions described above may be incorporated in the nurses' station that serves the postpartum patient rooms.

(iii) **Neonate examination and treatment areas.** Such areas, when required by the functional program, shall contain:

(a) A work counter;

(b) Storage facilities; and

(c) A hands-free handwashing station.

(iv) **Neonate formula facilities.**

(a) Where infant formula is prepared onsite, direct access from the formula preparation room to any nursery room is prohibited.

(b) The room may be located near the nursery or at other appropriate locations in the hospital, but shall include:

(1)(A) Cleanup facilities for washing and sterilizing supplies.

(B) This area shall include:

(i) A handwashing station;

(ii) Facilities for bottle washing;

(iii) A work counter; and

(iv) Sterilization equipment;

(2)(A) Separate room for preparing infant formula.

(B) This room shall contain:

(i) Warming facilities;

(ii) Refrigerator;

(iii) Work counter;

(iv) Formula sterilizer;

(v) Storage facilities; and

(vi) A handwashing station; and

(3) Refrigerated storage and warming facilities for infant formula accessible for use by nursery personnel at all times;

(8)(A) Commercial neonate formula.

(B) If a commercial infant formula is used, the separate cleanup and preparation rooms may be omitted.

(C) The storage and handling may be done in:

(i) The nursery workroom; or

(ii) Another appropriate room in the hospital that is conveniently accessible at all hours.

(D) The preparation area shall have:

(i) A work counter;

(ii) A handwashing station; and

(iii) Storage facilities;

(9)(A) Housekeeping/environmental services room.

(B) A housekeeping/environmental services room shall be provided for the exclusive use of the nursery unit.

(C) It shall:

(i) Be directly accessible from the unit;

(ii) Contain a service sink or floor receptor; and

(iii) Provide for storage of supplies and housekeeping equipment; and

(10)(A) Charting space.

(B) Charting facilities shall have linear surface space to ensure that staff and physicians may chart and have simultaneous access to information and communication systems.

(c) Newborn nursery.

(1)(A) Each newborn nursery room shall contain no more than sixteen (16) stations.

(B) The minimum floor areas shall be twenty-four square feet (24 sq. ft.) per bassinet, exclusive of auxiliary work areas.

(C) When a rooming-in program is used, the total number of bassinets provided in these units may be appropriately reduced, but the newborn nursery shall not be omitted in its entirety from any facility that includes delivery services.

(D) When facilities use a rooming-in program in which all infants are returned to the nursery at night, a reduction in nursery size may not be practical.

(2)(A) Baby-holding nurseries may replace traditional nurseries with baby-holding nurseries in postpartum and labor-delivery-recovery-postpartum units.

(B) The minimum floor area per bassinet, ventilation, electrical, and medical vacuum and gases shall be the same as that required for a full-term nursery.

(C) These holding nurseries should be next to the nurses' station on these units.

(D) The holding nursery shall be sized to accommodate the percentage of newborns who do not remain with their mothers during the postpartum stay.

(d) **Continuing care nursery.** For hospitals that provide continuing care for infants requiring close observation (for example, low birthweight babies who are not ill but require more hours of nursing than do normal neonates), the minimum floor space shall be fifty square feet (50 sq. ft.) per bassinet, exclusive of auxiliary work areas, with provisions for at least four feet (4') between and at all sides of each bassinet.

(e) **Pediatric nursery.**

(1)(A) To minimize the possibility of cross-infection, each nursery room serving pediatric patients shall contain no more than eight (8) bassinets.

(B) Each bassinet shall have a minimum clear floor area of forty square feet (40 sq. ft.).

(2) Each room shall contain:

(A) A lavatory equipped for hands-free handwashing;

(B) A nurses' emergency calling system; and

(C) A glazed viewing window for observing infants from public areas and workrooms.

(3) Limitation on number of patients in a nursery room does not apply to the pediatric critical care unit.

20 CAR § 43-146. Physical facilities — Pediatric and adolescent unit.

The unit shall meet the following standards:

(1) **Patient rooms.** Each patient room shall meet the following standards:

(A) Maximum room capacity shall be four (4) patients;

(B)(i) The space requirements for pediatric patient beds shall be the same as for adult beds due to the:

(a) Size variation; and

(b) Need to change from cribs to beds and vice-versa.

(ii) See 20 CAR § 43-143, physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease, for requirements.

(iii) Additional provisions for hygiene, toilets, sleeping, and personal belongings shall be included where the program indicates that parents will be allowed to remain with young children.

(iv) See 20 CAR § 43-144, physical facilities — critical care unit, and 20 CAR § 43-145, physical facilities — nursery units for:

(a) Pediatric critical care units; and

(b) Newborn nurseries; and

(C) Each patient room shall have a window in accordance with 20 CAR § 43-143, physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease; and

(2) Examination/treatment rooms.

(A) This room shall be provided for pediatric and adolescent patients.

(B) A separate area for infant examination and treatment may be provided within the pediatric nursery workroom.

(C) Examination/treatment rooms shall have a minimum floor area of one hundred twenty square feet (120 sq. ft.).

(D) The room shall contain:

(i) A handwashing fixture;

(ii) Storage facilities; and

(iii) A desk, counter, or shelf space for writing.

(E) This room is not required if all rooms are private.

(F)(i) Multipurpose or individual room or rooms shall be provided within or adjacent to areas serving pediatric and adolescent patients for dining, education, and developmentally appropriate play and recreation, with access and equipment for patients with physical restrictions.

(ii) If the functional program requires, an individual room shall be provided to allow for confidential parent/family:

(a) Comfort;

(b) Consultation; and

(c) Teaching.

(iii) Insulation, isolation, and structural provisions shall minimize the transmission of impact noise through the floor, walls, or ceiling of these multipurpose room or rooms.

(G)(i) Space for preparation and storage of infant formula shall be provided within:

(a) The unit; or

(b) Other convenient location.

(ii) Provisions shall be made for continuation of special formula that may have been prescribed for the infant prior to admission or readmission.

(H) Patient toilet room or rooms with handwashing stations in each room, in addition to those serving bed areas, shall be conveniently located to:

(i) Multipurpose room or rooms; and

(ii) Each central bathing facility.

(I) Storage closets or cabinets for toys and educational and recreational equipment shall be provided.

(J)(i) Storage space shall be provided to permit exchange of cribs and adult beds.

(ii) Provisions shall also be made for storage of equipment and supplies, including cots or recliners, extra linen, etc., for parents who stay with the patient overnight.

(K)(i) A least one (1) airborne infection isolation room shall be provided in each pediatric unit.

(ii) The total number of infection isolation rooms shall be determined by an infection prevention and control risk assessment.

(iii) Airborne infection isolation room or rooms shall comply with the requirements of 20 CAR § 43-143(d), physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease.

(L) Separate clean and soiled workrooms or holding rooms shall be provided as described in 20 CAR § 43-143(c)(3)(H) and (c)(3)(I), physical facilities —

patient accommodations — adult medical, surgical — communicable or pulmonary disease.

20 CAR § 43-147. Physical facilities — Psychiatric nursing unit.

(a)(1) When part of a general hospital, these units shall be designed for the care of inpatients.

(2) Nonambulatory inpatients may be treated in a medical unit until their medical condition allows for transfer to the psychiatric nursing unit.

(3) Provisions shall be made in the design for adapting the area for various types of psychiatric therapies.

(b)(1) The environment of the unit should be characterized by a feeling of openness with emphasis on natural light and exterior views.

(2) Various functions should be accessible from common areas while not compromising desirable levels of patient privacy.

(3)(A) Interior finishes, lighting, and furnishings should suggest a residential rather than an institutional setting.

(B) These should, however, conform with applicable fire safety codes.

(4) Security and safety devices should not be presented in a manner to attract or challenge tampering by patients.

(c) Where glass fragments pose a hazard to certain patients, safety glazing and/or other appropriate security features shall be used.

(d) Details of such facilities should be as described in the approved functional program.

(e) Each nursing unit shall provide the following:

(1)(A) Patient rooms.

(B) The patient room requirements noted in 20 CAR § 43-143, physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease, shall be applied to patient rooms in psychiatric nursing units except as follows:

(i) A nurses' call system is not required, but if it is included, provisions shall be made for:

(a) Easy removal; or

(b) Covering call button outlets;

(ii) Bedpan flushing devices shall be omitted from patient room toilets;

(iii) Handwashing stations are not required in patient rooms;

(iv) Visual privacy in multibed rooms (e.g., cubicle curtains) is not required;

(v) The ceiling and the air distribution devices, lighting fixtures, sprinkler heads, and other appurtenances shall be of a tamper-resistant type;

(vi) Each patient room shall be provided with a private toilet that meets the following requirements:

(a) The door shall not be lockable from within;

(b) The door shall be capable of swinging outward; and

(c) The ceiling shall be of tamper-resistant construction and the air distribution devices, lighting fixtures, sprinkler heads, and other appurtenances shall be of the tamper-resistant type; and

(vii)(a) Patient rooms, exclusive of toilet rooms, closets, lockers, wardrobes, alcoves, or vestibules, shall be at least:

(1) One hundred square feet (100 sq. ft.) for single bedrooms; and

(2) Eighty square feet (80 sq. ft.) per bed for multiple-bed rooms.

(b) The dimensions and room arrangement criteria of 20 CAR § 43-143 does not apply;

(2) **Service areas.** The standards noted in 20 CAR § 43-143, physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease, shall apply to service areas for psychiatric nursing units with the following modifications:

(A)(i) A secured storage area shall be provided for patients' belongings that are determined to be potentially harmful (e.g., razors, nail files, cigarette lighters).

(ii) This area shall be controlled by staff;

(B) Medication station shall include provisions for security against unauthorized access;

(C) Food service within the unit may be one (1) or a combination of the following:

(i) A nourishment station; and

(ii) A kitchenette designed for patient use with staff control of heating and cooking devices;

(D) Storage space for stretchers and wheelchairs may be outside the psychiatric unit, provided that provisions are made for convenient access as needed for disabled patients;

(E)(i) In psychiatric nursing units, a bathtub or shower shall be provided for every six (6) beds not otherwise served by bathing facilities within the patient rooms.

(ii) Bathing facilities shall be designed and located for patient convenience and privacy;

(F)(i) A separate charting area shall be provided with provisions for acoustical privacy.

(ii) A viewing window to permit observation of patient areas by the charting nurse or physician may be used if the arrangement is such that patient files cannot be read from outside the charting space;

(G)(i) At least two (2) separate social spaces, one (1) appropriate for noisy activities and one (1) for quiet activities, shall be provided.

(ii) The combined area shall be a minimum of forty square feet (40 sq. ft.) per patient with a minimum of one hundred twenty square feet (120 sq. ft.) for each of the two (2) spaces.

(iii) This space may be shared by dining activities;

(H)(i) Space for group therapy shall be provided.

(ii) This may be combined with the quiet space noted above in subdivision(e)(2)(G) of this section when the unit accommodates not more than twelve (12) patients and when at least two hundred twenty-five square feet (225 sq. ft.) of enclosed private space is available for group therapy activities;

(I)(i) Patient laundry facilities with an automatic washer and dryer shall be provided.

(ii) The following elements shall also be provided, but may be either within the psychiatric unit or immediately accessible to it unless otherwise dictated by the functional program;

(J)(i) A room or rooms for examination and treatment shall have a minimum floor area of one hundred twenty square feet (120 sq. ft.).

(ii) Examination and treatment room or rooms for medical-surgical patients may be shared by the psychiatric unit patients.

(iii) These may be on a different floor if conveniently accessible;

(K)(i) Separate consultation room or rooms with minimum floor space of one hundred square feet (100 sq. ft.) each, provided at a room-to-bed ratio of one (1) consultation room for every twelve (12) psychiatric beds.

(ii) The room or rooms shall be:

(a) Designed for acoustical and visual privacy; and

(b) Constructed to achieve a noise reduction of at least forty-five (45) decibels.

(iii) This room is not required if all rooms are private;

(L)(i) Psychiatric units each containing fifteen square feet (15 sq. ft.) of separate space per patient for patient therapy/multipurpose use, with a minimum total area of at least two hundred square feet (200 sq. ft.), whichever is greater.

(ii) Space shall include provision for:

(a) Handwashing;

(b) Work counter or counters;

(c) Storage; and

(d) Displays.

(iii) This space may serve more than one (1) nursing unit.

(iv) When psychiatric nursing unit or units contain fewer than twelve (12) beds, the therapy and other functions may be performed within the noisy activities area if at least an additional ten square feet (10 sq. ft.) per patient served is included; and

(M) A conference and treatment planning room for use by the psychiatric unit; and

(3) Seclusion treatment room.

(A) There shall be at least one (1) seclusion room for:

(i) Up to twenty-four (24) beds; or

(ii) A major fraction thereof.

(B) If a facility has more than one (1) psychiatric nursing unit, the number of seclusion rooms shall be a function of the total number of psychiatric beds in the facility.

(C)(i) Seclusion rooms may be grouped together.

(ii)(a) The seclusion room is intended for short-term occupancy by a violent or suicidal patient.

(b) The room or rooms shall be located for direct nursing staff supervision.

(c) Each room shall be for only one (1) patient.

(d) It shall:

(1) Have an area of at least sixty square feet (60 sq. ft.);

and

(2) Be constructed to prevent patient:

(A) Hiding;

(B) Escape;

(C) Injury; or

(D) Suicide.

(e) Where restraint beds are required by the functional program, eighty square feet (80 sq. ft.) shall be required.

(iii)(a) Room doors shall be designed with hardware that will permit the doors to swing out.

(b) Outside corners shall be omitted where possible.

(c) The ceiling shall be of tamper-resistant construction and the air distribution devices, lighting fixtures, sprinkler heads, and other appurtenances shall be of the tamper-resistant type.

(d) The walls shall be completely free of objects.

(e) Special fixtures and hardware for electrical circuits shall be used.

(f) Minimum ceiling height shall be nine feet (9').

(g) Doors shall:

(1) Be three feet eight inches (3' 8") wide; and

(2) Permit staff observation of the patient while also maintaining provisions for patient privacy.

(h) Seclusion treatment rooms shall be accessed by an anteroom or vestibule that also provides direct access to a toilet room.

(i) The toilet room and anteroom shall provide for safe management of the patient.

(iv)(a) Where the interior of the seclusion room is padded with combustible materials, these materials shall be of a type acceptable to NFPA standards.

(b) The room area including floor, walls, ceilings, and all openings shall be protected with not less than one-hour-rated construction.

20 CAR § 43-148. Physical facilities — Surgical facilities.

(a) General operating room or rooms.

(1) At least one (1) general operating room shall be provided for every fifty (50) beds or major fraction thereof up to two hundred (200) beds.

(2) Over two hundred (200) beds, additional operating room needs shall be based on the projected surgical workload.

(3) In new construction, each room shall have a minimum clear area of four hundred square feet (400 sq. ft.) exclusive of fixed or wall-mounted cabinets and built-in shelves, with a:

(A) Minimum of twenty feet (20') clear dimension between fixed cabinets and built-in shelves; and

(B) System for emergency communication with the surgical suite control station.

(4) X-ray film illuminators for handling at least four (4) films simultaneously shall also be provided.

(5) In renovation projects, every effort shall be made to meet the floor space requirements indicated above.

(6) In no event shall the clear floor area be less than three hundred sixty square feet (360 sq. ft.) with a minimum dimension of eighteen feet (18').

(b) Specialty operating rooms for cardiovascular, orthopedic, neurological, and other procedures that require additional personnel and/or large equipment.

(1) When included, this room shall have in addition to the above requirements for general operating rooms a minimum clear area of six hundred square feet (600 sq. ft.) with a minimum of twenty feet (20') clear dimension exclusive of fixed or wall-mounted cabinets and built-in shelves.

(2) When open-heart surgery is performed, an additional room in the restricted area of the surgical suite shall be designated as a pump room where extracorporeal pump or pumps, supplies, and accessories are stored and serviced.

(3) When complex orthopedic and neurosurgical surgery is performed, additional rooms shall be in the restricted area of the surgical suite that shall be designated as equipment storage rooms for the large equipment used to support these procedures.

(4) Appropriate plumbing, medical gases, and electrical connections shall be provided in the pump storage room.

(5) When included, a room for orthopedic surgery shall, in addition to the above, have enclosed storage space for splints and traction equipment.

(6) Storage outside the operating room shall be conveniently located.

(7) If a sink is used for the disposal of casting material, an appropriate trap shall be provided.

(8) In renovation projects, every effort shall be made to meet the floor space requirements indicated above.

(9) In no event shall the clear floor area be less than four hundred square feet (400 sq. ft.), except orthopedic procedures shall be three hundred sixty square feet (360 sq. ft.) with a minimum dimension of eighteen feet (18').

(c) Room or rooms for surgical cystoscopic and endo-urologic procedures.

(1) When provided and/or required by the written functional program, the cystoscopic and endo-urologic procedures room or rooms shall follow these requirements.

(2) A scrub sink or large lavatory shall be provided within or adjoining the cystoscopy room.

(3) In new construction, these rooms shall have a minimum clear area of three hundred fifty square feet (350 sq. ft.) exclusive of fixed or wall-mounted cabinets and built-in shelves, with a minimum of fifteen feet (15') clear dimension between fixed cabinets and built-in shelves.

(4) Additional clear space may be required by the functional program to accommodate special functions in one (1) or more of these rooms.

(5) An emergency communications system shall connect with the surgical suite control station.

(6) Facilities for the disposal of liquid wastes shall be provided.

(7) If a floor drain is installed to provide for disposal of liquid wastes, it shall be completely insulated from ground by means of:

(A) An insulating-type floor drain; and

(B) Nonconductive waste connections.

(8) The drain shall also be provided with a flushing device.

(9) X-ray viewing capability to accommodate at least four (4) films simultaneously shall be provided.

(10) In renovation projects, every effort shall be made to meet the clear floor space requirements indicated above for construction.

(11) In no event shall the clear floor space be less than two hundred fifty square feet (250 sq. ft.).

(d) **Endoscopy.**

(1) The endoscopy suite may be divided into three (3) major functional areas:

(A) The procedure room or rooms;

(B) The instrument processing room or rooms; and

(C) The patient holding/preparation and recovery room or area.

(2) **Note.**

(A) When invasive procedures are to be performed in this unit on persons who are known or suspected of having airborne infectious diseases, these procedures should not be performed in the operating suite.

(B) These procedures shall be performed in a:

(i) Room meeting airborne infections isolation ventilation requirements; or

(ii) Space using local exhaust ventilation.

(C) **Procedures room or rooms.**

(i) Each procedure room shall have a minimum clear area of two hundred square feet (200 sq. ft.) (fifteen and fifty-eight hundredths square meters (15.58 sq. m.)) exclusive of fixed cabinets and built-in shelves.

(ii) A freestanding handwashing fixture with hands-free controls shall be available in the suite.

(iii) Refer to Table 10 of Appendix A for medical gas station outlets.

(iv) Floor covering shall be monolithic and joint-free.

(v) A system for emergency communication shall be provided.

(vi) Procedure rooms shall be designed for visual and acoustical privacy for the patient.

(D) Instrument processing room or rooms.

(i)(a) Dedicated processing room or rooms for cleaning and disinfecting instrumentation shall be provided.

(b) In an optimal situation, cleaning room or rooms shall be located between two (2) procedure rooms.

(c) However, one (1) processing room may serve multiple procedure rooms.

(d) Size of the cleaning room or rooms is dictated by the amount of equipment to be processed.

(e) Cleaning rooms shall allow for flow of instrumentations from the contaminated area to the clean area, and finally to storage.

(f) The clean equipment rooms, including storage, should protect the equipment from contamination.

(ii) The decontamination room shall be equipped with the following:

(a) Two (2) utility sinks remote from each other;

(b) One (1) freestanding handwashing fixture;

(c) Work counter space or spaces;

(d) Space and plumbing fixtures for automatic endoscope cleaners, sonic processor, and flash sterilizers, where required;

(e)(1) Ventilation system.

(2) Negative pressure shall be maintained and minimum of ten (10) air changes per hour shall be maintained.

(3) A hood is recommended over the work counter.

(4) All air shall be exhausted to the outside to avoid recirculation within the facility;

(f) Outlets for vacuum and compressed air; and

(g) Floor covering shall be monolithic and joint-free.

(iii) **Patient holding/prep/recovery area.** The following elements shall be provided in this area:

(a) Each patient cubicle shall be equipped with oxygen and suction outlets;

(b) Cubicle curtains for patient privacy;

(c) Medication preparation and storage with handwashing stations;

(d) Toilet facilities (may be accessible from patient holding or directly from procedure room or rooms or both);

(e) Change areas and storage for patients' personal effects;

(f) Nurses' reception and charting area with visualization of patients;

(g) Clean utility room or area; and

(h) Environmental services closet.

(e) **Service areas.**

(1) Individual rooms shall be provided when so noted, otherwise alcoves or other open spaces that shall not interfere with traffic may be used.

(2) Services, except the soiled workroom and the janitor's closet, may be shared with and organized as part of the obstetrical facilities if the approved functional program reflects this sharing concept.

(3) Service areas shall be arranged to avoid direct traffic between the operating and delivery suites.

(4) The following areas shall be provided:

(A) Control station located to permit visual surveillance of all traffic that enters the operating suite;

(B)(i) A supervisor's office or station.

(ii) The number of offices, stations, and teaching areas in the surgical suite shall depend upon the functional program;

(C)(i) Sterilizing facilities conveniently located to serve all operating rooms.

(ii) The sterilizing facility shall have:

(a) Work counter space; and

(b) A handwashing sink.

(iii) When the functional program indicates that adequate provisions have been made for replacement of sterile instruments during surgery, sterilization facilities in the surgical suite shall not be required;

(D)(i) Medication distribution.

(ii) Provisions shall be made for storage and distribution of medications.

(iii) This may be done from a medication preparation room or unit, from a self-contained medication dispensing unit, or by another system approved by the Department of Health.

(iv) If used, a medication preparation room or unit shall be under visual control of nursing staff.

(v) It shall contain a work counter, sink, refrigerator, and double-locked storage for controlled substances with convenient access to handwashing stations provided.

(vi) Each blood bank refrigerator shall be on an emergency power circuit;

(E)(i) Scrub facilities.

(ii)(a) Two (2) scrub stations shall be provided near the entrance to each operating room.

(b) However, two (2) scrub stations may serve two (2) operating rooms if the scrub stations are located adjacent to the entrance of each operating room.

(iii) Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts.

(iv) In new construction, view windows at scrub stations permitting observation of room interiors shall be provided.

(v) The scrub sinks shall be recessed into an alcove out of the main traffic areas.

(vi) Equipment and supplies for timed scrub technique shall be available at each scrub sink with manual and/or automatic two-way controls;

(F)(i) Soiled workroom.

(ii) An enclosed soiled workroom, or soiled-holding room that is part of a system for the collection and disposal of soiled material for the exclusive use of the surgical suite shall be provided.

(iii) It shall be located in the restricted area.

(iv) The soiled workroom shall contain:

(a) A flushing-rim clinical sink or equivalent flushing-rim fixture;

(b) A work counter;

(c) A handwashing fixture; and

(d) Space for waste receptacles and soiled linen receptacles.

(v) Rooms used only for temporary holding of soiled material may omit the flushing-rim clinical sink and work counters.

(vi) However, if the flushing-rim clinical sink is omitted, other provisions for disposal of liquid waste shall be provided.

(vii) This room shall not have direct connection with:

(a) Operating rooms; or

(b) Other sterile activity rooms.

(viii) Soiled and clean workrooms or holding rooms shall be separated;

(G)(i) Clean workroom or a clean supply room.

(ii) A clean workroom is required when clean materials are assembled within the surgical suite prior to use, or following the decontamination cycle.

(iii) It shall contain:

(a) A work counter;

(b) A handwashing fixture;

(c) Storage for clean supplies; and

(d) Space to package reusable items.

(iv) The storage for sterile supplies shall be separated from this space.

(v) If the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixture may be omitted.

(vi) Storage space for sterile and clean supplies shall be adequate for the functional plan.

(vii) The space shall be:

(a) Moisture-controlled and temperature-controlled; and

(b) Free from cross-traffic;

(H)(i) The location of sterilization for surgical instruments and the direction of flow from the decontamination location to the sterile location shall be addressed by the written functional program.

(ii) An operating room suite design with a sterile core shall provide for no cross-traffic of staff and supplies from the decontaminated/soiled areas to the sterile/clean areas.

(iii)(a) The use of facilities outside the operating room for soiled/decontaminated processing and clean assembly and sterile processing shall be designed to move the flow of goods and personnel from dirty to clean/sterile without compromising standard precautions or aseptic techniques in both departments.

(b) This room shall have no direct opening into an operating room;

(I) Anesthesia storage shall be provided in accordance with NFPA 99;

(J)(i) Medical gas storage facilities.

(ii) Main storage of medical gases may be outside or inside the facility in accordance with NFPA 99.

(iii) Provision shall be made for additional separate storage of reserve gas cylinders necessary to complete at least one (1) day's procedures;

(K) An anesthesia workroom for testing and storing anesthesia equipment shall contain:

- (i) A work counter;
- (ii) A sink; and
- (iii) Racks for cylinders;

(L)(i) Equipment storage room or rooms for equipment and supplies used in the surgical suite.

(ii) Each surgical suite shall provide sufficient storage area to keep the exit access corridor free of equipment and supplies, but not less than one hundred fifty square feet (150 sq. ft.) or fifty square feet (50 sq. ft.) per OR, whichever is greater;

(M)(i) Staff dressing room.

(ii) Appropriate room or rooms shall be provided for males and females working within the surgical suite.

(iii) The room or rooms shall contain:

- (a) Lockers;
- (b) Showers;
- (c) Toilets;
- (d) Lavatories equipped for handwashing; and
- (e) Space for donning scrub suits and boots.

(iv) This room or these rooms shall be arranged to provide a one-way traffic pattern so personnel entering from outside the surgical suite can:

- (a) Change;
- (b) Shower;
- (c) Gown; and
- (d) Move directly into the surgical suite;

(N) Stretcher storage area out of direct line of traffic;

(O)(i) Staff lounge and toilet facilities.

(ii) Separate or combined lounges for males and females shall be provided.

(iii) A lounge or lounges shall be located to:

- (a) Permit use without leaving the surgical suite; and

(x) Handwashing stations with hands-free operable controls shall be available with at least one (1) for every four (4) lounge chairs uniformly distributed to provide equal access from each patient bed;

(R)(i) Change areas for outpatients and same-day admissions.

(ii) If the functional program defines outpatient surgery as part of the surgical suite, a separate area shall be provided where outpatients may:

(a) Change from street clothing into hospital gowns; and

(b) Be prepared for surgery.

(iii) This would include a:

(a) Waiting room;

(b) Locker or lockers;

(c) Toilet or toilets; and

(d) Clothing change or gowning area.

(iv) Changing may also be accommodated in a private holding room or cubicle;

(S) Provisions shall be made for:

(i) Patient examination;

(ii) Interviews;

(iii) Preparation;

(iv) Testing; and

(v) Obtaining vital signs of patients for outpatient surgery;

(T)(i) Patient holding area.

(ii) In facilities with two (2) or more operating rooms, an area shall be provided to accommodate stretcher patients waiting for surgery.

(iii) This holding area shall be under the visual control of the nursing staff;

(U)(i) Storage areas for portable X-ray equipment, stretchers, fracture tables, warming devices, auxiliary lamps, etc.

(ii) These areas shall be out of corridors and traffic;

(V) Emergency equipment storage under direct control of the nursing staff and not obstructing the corridor;

(W)(i) Environmental services closet.

(ii) See 20 CAR § 43-164, physical facilities — cleaning and sanitizing carts, employee facilities, and environmental closets, for detailed requirements;

(X)(i) Area for preparation and examination of frozen sections.

(ii) This may be part of the general laboratory if immediate results are obtainable without unnecessary delay in the completion of surgery;

(Y)(i) Ice machine.

(ii) An ice machine shall be provided to provide ice for treatments and patient use.

(iii) Ice intended for human consumption shall be from self-dispensing icemakers;

(Z)(i) A waiting room with toilets, telephones, and drinking fountains conveniently located.

(ii) The toilet room shall contain handwashing stations.

(iii) If outpatients, as defined by the written functional program, are required to wait in this area then a separate area shall be provided.

(iv) Provisions shall be made for:

(a) Examinations;

(b) Interviews;

(c) Testing; and

(d) Obtaining vital signs.

(v) A separate area shall be provided where outpatients may change from street clothing into hospital gowns; and

(AA)(i) Ethylene oxide sterilization facilities.

(ii) Where ethylene oxide is used for sterilization, provisions shall be made for complete exhaust of gases to the exterior.

(iii) When the door is opened, arrangement shall ensure that gases are pulled away from the operator.

(iv) Provisions shall be made for appropriate aeration of supplies.

(v) Aeration cabinets shall be vented to the outside.

(vi) Where aeration cabinets are not used in ethylene oxide processing, provision for isolated area mechanically vented to the outside for aeration, Occupational Safety and Health Administration standards shall be met.

(f) Preoperative patient holding area or areas.

(1) In facilities with two (2) or more operating rooms, areas shall be provided to accommodate stretcher patients as well as sitting space for ambulatory patients not requiring stretchers.

(2) These areas:

(A) Shall be under the direct visual control of the nursing staff; and

(B) May be part of the recovery suite to achieve maximum flexibility in managing surgical caseloads.

(3) Each stretcher station shall:

(A) Be a minimum of eighty square feet (80 sq. ft.); and

(B) Have a minimum clearance of four feet (4') on the:

(i) Sides of the stretchers; and

(ii) Foot of the stretcher.

(4) Provisions shall be made for the isolation of infectious patients.

(5) Provisions for patient privacy, such as cubicle curtains, shall be made.

(g) Postanesthetic care units (PACUs).

(1)(A) Each PACU shall contain:

(i) A medication station;

(ii) Handwashing stations;

(iii) A nurses' station with charting facilities;

(iv) A clinical sink;

(v) Provisions for bedpan cleaning; and

(vi) Storage space for:

(a) Stretchers;

(b) Supplies; and

(c) Equipment.

(B) Additionally, the design shall provide a minimum of eighty square feet (80 sq. ft.) for each patient bed with a space for:

(i) Additional equipment described in the functional program; and

(ii) Clearance of at least:

(a) Five feet (5') between patient beds; and

(b) Four feet (4') between patient bedsides and adjacent walls.

(C) Provisions shall be made for the isolation of infectious patients.

(D) Provisions for patient privacy, such as cubicle curtains, shall be made.

(E) In new construction, at least one (1) door to the recovery room shall access directly from the surgical suite without crossing public hospital corridors.

(2)(A) An airborne infection isolation room is not required in a PACU.

(B) Provision for the recovery of a potentially infectious patient with an airborne infection shall be determined by the infection prevention and control risk assessment.

(3) A staff toilet shall be located within the working area to maintain staff availability to patients.

(4) Handwashing stations with hands-free operable controls shall be available with at least one (1) for every four (4) beds, uniformly distributed to provide equal access from each patient bed.

20 CAR § 43-149. Physical facilities — Obstetrical facilities.

(a) General.

(1) The obstetrical unit shall be located and designated to prohibit nonrelated traffic through the unit.

(2) When delivery and operating rooms are in the same suite, access and service arrangements shall be such that neither staff nor patients need to travel through one (1) area to reach the other.

(3) Except as permitted otherwise herein, existing facilities being renovated shall, as far as practicable, provide all the required support services.

(b) Postpartum unit.

(1) Postpartum room.

(A)(i) A postpartum room shall have a minimum of:

(a) One hundred square feet (100 sq. ft.) of clear floor area per bed in multibedded rooms; and

(b) One hundred twenty square feet (120 sq. ft.) of clear floor area in single-bed rooms.

(ii) These areas shall be exclusive of:

(a) Toilet rooms;

(b) Closets;

(c) Alcoves; or

(d) Vestibules.

(iii) Where renovation work is undertaken, every effort shall be made to meet the above minimum standards.

(iv) If it is not possible to meet the above square-foot standards, the authorities having jurisdiction may grant approval to deviate from this requirement.

(v) In such cases, existing postpartum patient rooms shall have no less than:

(a) Eighty square feet (80 sq. ft.) of clear floor area per bed in multiple-bed rooms; and

(b) One hundred square feet (100 sq. ft.) in single-bed rooms.

(B) In multibedded rooms there shall be a minimum clear distance of:

(i) Four feet (4') between the foot of the bed and the opposite wall;

(ii) Three feet (3') between the side of the bed and nearest wall; and

(iii) Four feet (4') between beds.

(C) The maximum number of beds per room shall be two (2).

(2) The following support services for this unit shall be provided:

(A) Nurses' station;

(B) Nurse office;

(C) Charting facilities;

- (D) Toilet room for staff;
- (E) Staff lounge;
- (F) Lockable closets or cabinets for personal articles of staff;
- (G) Consultation/conference room or rooms;
- (H)(i) Patients' lounge.

(ii) The patients' lounge may be omitted if all rooms are single-bedded rooms;

- (I)(i) Clean workroom or clean supply room.

(ii) A clean workroom is required if clean materials are assembled within the obstetrical suite prior to use.

(iii) It shall contain a work counter, a handwashing fixture, and storage facilities for clean and sterile supplies.

(iv) If the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixtures may be omitted.

- (v) Soiled and clean workrooms or holding rooms shall:

(a) Be separated; and

(b) Have no direct connection;

(J)(i) Soiled workroom or soiled holding room for the exclusive use of the obstetrical suite.

- (ii) This room shall be separate from the clean workroom.

- (iii) The soiled workroom shall contain:

(a) A clinical sink or equivalent flushing-rim fixture; and

(b) A handwashing fixture.

- (iv) The above fixtures shall have a hot and cold mixing faucet.

- (v) The room shall have:

(a) A work counter; and

(b) Space for separate covered containers for soiled linen and waste.

(vi) Rooms used only for temporary holding of soiled material may omit the clinical sink and work counter.

(vii) If the flushing-rim clinical sink is omitted, facilities for cleaning bedpans shall be provided elsewhere;

(K)(i) Medication station.

(ii) Provision shall be made for storage and distribution of drugs and routine medications.

(iii) This may be done:

(a) From a medicine preparation room or unit;

(b) From a self-contained medicine dispensing unit; or

(c) By another approved system.

(iv) If used, a medicine preparation room or unit shall be under visual control of nursing staff.

(v) It shall contain:

(a) A work counter;

(b) A sink;

(c) A refrigerator; and

(d) Double-locked storage for controlled substances.

(vi) Convenient access to handwashing stations shall be provided.

(vii) Standard cup-sinks provided in many self-contained units are not adequate for handwashing;

(L)(i) Clean linen storage may be part of a clean workroom or a separate closet.

(ii) When a closed cart system is used, the cart shall be stored out of the path of normal traffic;

(M)(i) Nourishment station shall contain:

(a) A sink;

(b) A work counter;

(c) An ice dispenser;

(d) A refrigerator;

(e) Cabinets; and

(f) Equipment for serving hot or cold food.

(ii) Space shall be included for temporary holding of unused or soiled dietary trays;

(N)(i) Equipment storage room.

(ii) Each unit shall provide sufficient storage area or areas located on the patient floor to keep its required corridor width free of equipment and supplies, but not less than:

(a) Ten square feet (10 sq. ft.) per postpartum room; and

(b) Twenty square feet (20 sq. ft.) per each LDR or LDRP outside of the patient room;

(O) Storage space for stretchers and wheelchairs shall be provided in a strategic location out of corridors and away from normal traffic;

(P) When bathing facilities are not provided in patient rooms, there shall be at least one (1) shower and/or bathtub for every six (6) beds or fraction thereof;

(Q)(i) A housekeeping room shall be provided for the exclusive use of the obstetrical suite.

(ii) It shall be directly accessible from the suite and shall contain:

(a) A service sink or floor receptor; and

(b) Provisions for storage of supplies and housekeeping equipment;

(R)(i) Examination/treatment room and/or multipurpose diagnostic testing room shall have a minimum clear floor area of one hundred twenty square feet (120 sq. ft.).

(ii) When utilized as a multipatient diagnostic testing room, a minimum clear floor area of eighty square feet (80 sq. ft.) per patient shall be provided.

(iii) An adjoining toilet room shall be provided for patient use; and

(S) Emergency equipment storage shall be located in close proximity to the nurses' station.

(3) Airborne infection isolation room or rooms.

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(A) An airborne infection isolation room is not required for the obstetrical unit.

(B) Provisions for the care of the perinatal patient with an airborne infection shall be determined by the infection prevention and control risk assessment.

(c) Cesarean/delivery suite.

(1)(A) Cesarean/delivery room or rooms shall have a minimum clear floor area of three hundred sixty square feet (360 sq. ft.) with a minimum dimension of sixteen feet (16') exclusive of built-in shelves or cabinets.

(B) There shall be a minimum of one (1) such room in every obstetrical unit.

(2)(A) Delivery room or rooms shall have minimum clear area of three hundred square feet (300 sq. ft.) exclusive of fixed cabinets and built-in shelves.

(B) An emergency communication system shall be connected with the obstetrical suite control station.

(3)(A) Infant resuscitation:

(i) Shall be provided within the Cesarean/delivery room or rooms and delivery rooms with a minimum clear floor area of forty square feet (40 sq. ft.) in addition to the required area of each room; or

(ii) May be provided in a separate but immediately accessible room with a clear floor area of one hundred fifty square feet (150 sq. ft.).

(B) Six (6) single or three (3) duplex electrical outlets shall be provided for the infant in addition to the facilities required for the mother.

(4) Labor room or rooms — LDR or LDRP rooms may be substituted.

(A) In renovation projects, existing labor rooms may have a minimum clear area of one hundred square feet (100 sq. ft.) per bed.

(B) Where LDRs or LDRPs are not provided, a minimum of two (2) labor beds shall be provided for each Cesarean room and/or delivery room.

(C) In facilities that have only one (1) Cesarean delivery room, two (2) labor rooms shall be provided.

(D) Each room shall be designed for either one (1) or two (2) beds with a minimum clear area of one hundred twenty square feet (120 sq. ft.) per bed.

(E) Each labor room shall:

(i) Contain a handwashing fixture; and

(ii) Have access to a private toilet room.

(F) One (1) toilet room may serve two (2) labor rooms.

(G) Labor rooms shall have controlled access with doors that are arranged for observation from a nurses' station.

(H) At least one (1) shower, which may be separate from the labor room if under staff control, for use of patients in labor shall be provided.

(I) Windows in labor rooms, if provided, shall be located, draped, or otherwise arranged to preserve patient privacy from casual observation from outside the labor room.

(5) Recovery room or rooms — LDR or LDRP rooms may be substituted.

(A) Each recovery room shall:

(i) Contain at least two (2) beds; and

(ii) Have a nurses' station with charting facilities located to permit visual control of all beds.

(B) Each room shall include stations for handwashing and dispensing medicine.

(C) A clinical sink with bedpan flushing device shall be available, as shall storage for supplies and equipment.

(D) There shall be:

(i) Enough space for baby and crib; and

(ii) A chair for the support person.

(E) There shall be the ability to maintain visual privacy of the new family.

(6) Service areas.

(A) Individual rooms shall be provided as indicated in the following standards, otherwise, alcoves or other open spaces that do not interfere with traffic may be used.

(B) The following services shall be provided:

(i) A control/nurses' station located to restrict unauthorized traffic into the suite;

(ii)(a) Soiled workroom or soiled holding room.

(b) This room shall be separate from the clean workroom.

(c) The soiled workroom shall contain a:

(1) Clinical sink; or

(2) Equivalent flushing-rim fixture.

(d) The room shall contain a handwashing fixture.

(e) The above fixtures shall have a hot and cold mixing faucet.

(f) The room shall have:

(1) A work counter; and

(2) Space for separate covered containers for soiled linen and waste.

(g) Rooms used only for temporary holding of soiled material may omit the clinical sink and work counter.

(h) If the flushing-rim clinical sink is eliminated, facilities for cleaning bedpans shall be provided elsewhere; and

(iii) Fluid waste disposal.

(C)(i) The following services may be shared with the surgical facilities if the functional program reflects this concern.

(ii) Where shared, areas shall be arranged to avoid direct traffic between the delivery and operating rooms:

(a) A supervisor's office or station;

(b)(1) A waiting room with toilets, telephones, and drinking fountains conveniently located.

(2) The toilet room shall contain handwashing stations;

(c)(1) Sterilizing facilities with high-speed sterilizers convenient to all Caesarean/delivery rooms.

(2) Sterilization facilities shall be:

(A) Separate from the delivery area; and

(B) Adjacent to clean assembly.

(3) High-speed autoclaves shall only be used in an emergency situation (i.e., a dropped instrument and no sterile replacement readily available).

(4) Sterilization facilities would not be necessary if the flow of materials were handled from a central service department based on the usage of the delivery room (DR);

(d) A drug distribution station with:

(1) Handwashing stations; and

(2) Provisions for:

(A) Controlled storage;

(B) Preparation; and

(C) Distribution of medication;

(e)(1) Scrub facilities for Caesarean and delivery rooms.

(2) Two (2) scrub stations shall be provided adjacent to the entrance to each Caesarean/delivery room.

(3) Scrub facilities should be arranged to minimize any splatter on nearby personnel or supply carts.

(4) In new construction, view windows at scrub stations to permit the observation of room interiors;

(f)(1) Clean workroom or clean supply room.

(2) A clean workroom shall be provided if clean materials are assembled within the obstetrical suite prior to use.

(3) If a clean workroom is provided it shall contain:

(A) A work counter;

(B) A sink equipped for handwashing; and

(C) Space for storage of supplies.

(4) A clean supply room may be provided when the narrative program defines a system for the storage and distribution of clean and sterile supplies;

(g)(1) Medical gas storage facilities.

(2) Main storage of medical gases may be outside or inside the facility in accordance with NFPA 99.

(3) Provision shall be made for additional separate storage of reserve gas cylinders necessary to complete at least one (1) day's procedures;

(h) A clean sterile storage area readily available to the delivery room, size to be determined on:

(1) Level of usage;

(2) Functions provided; and

(3) Supplies from the hospital central distribution area;

(i)(1) An anesthesia workroom for cleaning, testing, and storing anesthesia equipment.

(2) It shall contain:

(A) A work counter;

(B) A sink; and

(C) Provisions for separation of clean and soiled items;

(j) Equipment storage room or rooms for equipment and supplies used in the obstetrical suite;

(k)(1) Staff clothing change areas.

(2) The clothing change area shall be designed to encourage one-way traffic and cross-traffic between clean and contaminated personnel.

(3) The area shall contain:

(A) Lockers;

(B) Showers;

(C) Toilets;

(D) Handwashing stations; and

(E) Space for donning and disposing scrub suits and booties;

(I) Male and female support persons change area designed as described above;

(m)(1) Lounge and toilet facilities for obstetrical staff convenient to delivery, labor, and recovery areas.

(2) The toilet room shall contain handwashing stations;

(n) An on-call room or rooms for physician and/or staff may be located elsewhere in the facility;

(o)(1) Environmental services closet.

(2) See 20 CAR § 43-164, physical facilities — cleaning and sanitizing carts, employee facilities, and environmental closets, for detailed requirements; and

(p) An area for storing stretchers out of the path of normal traffic.

(d) LDR and LDRP facilities.

(1) When provided by the narrative program, delivery procedures in accordance with birthing concepts may be performed in the LDR or LDRP rooms.

(2) LDR room or rooms may be located:

(A) In a separate LDR suite; or

(B) As part of the Caesarean/delivery suite.

(3) The postpartum unit may contain LDRP rooms.

(4) These rooms shall have a minimum of two hundred fifty square feet (250 sq. ft.) of clear floor area with a minimum dimension of thirteen feet (13'), exclusive of:

(A) Toilet room;

(B) Closet;

(C) Alcove; or

(D) Vestibules.

(5) There should be enough space for a crib and reclining chair for a support person.

(6) An area within the room but distinct from the mother's area shall be provided for infant stabilization and resuscitation.

(7)(A) See Table 4 of Appendix A for medical gas outlets.

(B) These outlets shall be located in the room so that they are accessible to the:

(i) Mother's delivery area; and

(ii) Infant resuscitation area.

(8) When renovation work is undertaken, every effort shall be made to meet the above minimum standards.

(9) If it is not possible to meet the above square-foot standards, the authorities having jurisdiction may grant approval to deviate from this requirement.

(10) In such cases, existing LDR or LDRP rooms may have a minimum clear area of two hundred square feet (200 sq. ft.).

(11) Each LDR or LDRP room shall:

(A) Be for single occupancy; and

(B) Have direct access to a private toilet with shower or tub.

(12) Each room shall be equipped with handwashing facilities with hands-free operation area acceptable for scrubbing.

(13) Examination lights may be portable, but shall be immediately accessible.

(14) Finishes shall be selected:

(A) To facilitate cleaning; and

(B) With resistance to strong detergents.

(15) A window or windows shall be provided for LDRP room or rooms.

(16) Windows or doors within a normal sightline that would permit observation into the room shall be arranged or draped as necessary for patient privacy.

(17) Additional requirements for windows are provided above in subdivision (b)(2)(A) of this section.

20 CAR § 43-150. Physical facilities — Emergency suite.

General. The following shall be provided:

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(1)(A) Grade-level well-marked, illuminated, and covered entrance with direct access from public roads for ambulance and vehicle traffic.

(B) Entrance and driveway shall be clearly marked.

(C) If a raised platform is used for ambulance discharge, a ramp shall be provided for pedestrian and wheelchair access.

(D) The emergency vehicle entry cover shall provide shelter for both the patient and the emergency medical crew during transfer from an emergency vehicle into the building;

(2) Paved emergency access to permit discharge of patients from automobiles and ambulances and temporary parking convenient to the entrance;

(3)(A) Reception, triage, and nurses' station shall be located to permit staff observation and control of access to:

(i) Treatment area;

(ii) Pedestrian and ambulance entrances; and

(iii) Public waiting area.

(B) The triage area requires special consideration.

(C) As the point of entry and assessment for patients with undiagnosed and untreated airborne infections, the triage area shall be designed and ventilated to reduce exposure of staff, patients, and families to airborne infectious diseases.

(D) If determined by the infection prevention and control risk assessment, one (1) or more separate, enclosed spaces designed and ventilated as airborne infection isolation rooms shall be required;

(4)(A) Wheelchair and stretcher storage shall be provided for arriving patients.

(B) This shall be out of traffic with convenient access from emergency entrances;

(5)(A) Public waiting area with toilet facilities, drinking fountains, and telephones shall be provided.

(B) The hospital shall conduct infection prevention and control risk assessment to determine if the emergency department waiting area shall require special measures to reduce the risk of airborne infection transmission.

(C) These measures may include enhanced general ventilation and air disinfection similar to inpatient requirements for airborne infection isolation rooms;

(6) Communication center shall be convenient to nurses' station and have radio, telephone, and intercommunication systems;

(7)(A) Examination and treatment room or rooms.

(B) Examination and treatment room or rooms shall have a minimum floor area of one hundred twenty square feet (120 sq. ft.).

(C) The room shall contain:

(i) A work counter or counters;

(ii) Cabinets;

(iii) Handwashing stations;

(iv) Supply storage facilities;

(v) Examination lights;

(vi) A desk, counter, or shelf space for writing; and

(vii) A vision panel adjacent to and/or in the door.

(D) When treatment cubicles are in open multiple-bed areas, each cubicle shall:

(i) Have a minimum of eighty square feet (80 sq. ft.) of clear floor space; and

(ii) Shall be separated from adjoining cubicles by curtains.

(E) Handwashing stations shall be provided for every four (4) treatment cubicles or major fraction thereof in multiple-bed areas.

(F) For oxygen and vacuum requirements, see Table 4 of Appendix A.

(G) Treatment/exam rooms used for pelvic exams should allow for the foot of the examination table to face away from the door;

(8)(A) Trauma/cardiac rooms for emergency procedures, including emergency surgery, shall have at least two hundred fifty square feet (250 sq. ft.) of clear floor space.

(B) Each room shall have:

(i) Cabinets and emergency supply shelves;

- (ii) X-ray film illuminators;
- (iii) Examination lights; and
- (iv) Counter space for writing.

(C) Additional space with cubicle curtains for privacy may be provided to accommodate more than one (1) patient at a time in the trauma room.

(D) Provisions shall be made for monitoring the patient.

(E) There shall be storage provided for immediate access to attire used for universal precautions.

(F) Doorways leading from the ambulance entrance to the cardiac trauma room shall be a minimum of five feet (5') wide to simultaneously accommodate:

- (i) Stretchers;
- (ii) Equipment; and
- (iii) Personnel.

(G) In renovation projects, every effort shall be made to have existing cardiac/trauma rooms meet the above minimum standards;

(9)(A) Orthopedic and cast work.

(B) These may be in separate room or rooms or in the trauma room.

(C) They shall include:

- (i) Storage for splints and other orthopedic supplies;
- (ii) Traction hooks;
- (iii) X-ray film illuminators; and
- (iv) Examination lights.

(D) If a sink is used for the disposal of plaster of Paris, a plaster trap shall be provided.

(E) The clear floor space for this area shall depend on the:

- (i) Functions program; and
- (ii) Procedures and equipment accommodated here;

(10) Scrub stations located in or adjacent and convenient to each trauma and/or orthopedic room;

(11) Convenient access to radiology and laboratory services;

(12) Poison control center and EMS communications center may be part of the work and charting area;

(13)(A) Provisions for disposal of solid and liquid waste.

(B) This may be a clinical sink with bedpan flushing device within the soiled workroom;

(14) Storage area out of line of traffic for:

(A) Stretchers;

(B) Wheelchairs; and

(C) Emergency equipment;

(15)(A) A toilet room for patients.

(B) Where there are more than eight (8) treatment areas, a minimum of two (2) toilet facilities with handwashing station or stations in each toilet room will be required;

(16)(A) Soiled workroom for the exclusive use of the emergency suite.

(B) This room shall be separate from the clean workroom.

(C) The soiled workroom shall contain a:

(i) Clinical sink or equivalent flushing-type fixture;

(ii) Work counter;

(iii) Sink equipped for handwashing;

(iv) Waste receptacle; and

(v) Linen receptacle.

(D) This room shall:

(i) Be separate from the clean workroom; and

(ii) Have separate access doors;

(17)(A) Clean workroom or clean supply room.

(B) A clean workroom is required if clean materials are assembled within the emergency suite prior to use.

(C) It shall contain:

(i) A work counter;

(ii) A handwashing fixture; and

(iii) Storage facilities for clean and sterile supplies.

(D) If the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixtures may be omitted.

(E) Soiled and clean workrooms or holding rooms shall:

(i) Be separated; and

(ii) Have no direct connection;

(18)(A) Nurses' station or stations.

(B) Facilities for charting, clinical records, work counter, communication system, space for supplies, and convenient access to handwashing stations shall be provided.

(C) Visual observation of all traffic into the suite, where feasible;

(19) Securable closets or cabinet compartments for personnel;

(20)(A) Staff lounge.

(B) Convenient and private access to staff toilets, lounge, and lockers shall be provided;

(21)(A) Housekeeping room.

(B) A housekeeping room shall be directly accessible from the unit and shall contain:

(i) A service sink or floor receptor; and

(ii) Provisions for storage of supplies and housekeeping equipment;

(22)(A) Security station.

(B) A security system should be located near the emergency entrances and triage/reception area.

(C) The nonselective twenty-four-hour accessibility of the emergency dictates that a security system reflecting local community needs be provided;

(23)(A) At least one (1) airborne infection isolation room shall be provided.

(B) The need for additional airborne infection isolation rooms or for protective environment room shall be as determined by the infection prevention and control risk assessment.

- (C) See 20 CAR § 43-143(d) for requirements;
- (24)(A) Bereavement room shall be located within or adjacent to the emergency suite.
 - (B) A telephone shall be provided;
- (25)(A) Secured holding room in accordance with the functional program.
 - (B) At least one (1) holding/seclusion room of eighty square feet (80 sq. ft.) shall be provided.
- (C) This room shall allow for:
 - (i) Security;
 - (ii) Patient and staff safety;
 - (iii) Patient observations; and
 - (iv) Soundproofing; and
- (26)(A) Decontamination area.
 - (B) A decontamination area shall be provided.
 - (C) The functional program shall define the location of the area and the types of exposure (i.e., nuclear, biological, chemical) to be considered.
 - (D) The location of the area shall be permitted to be:
 - (i) On the exterior perimeter of the facility adjacent to the ambulance entrance; or
 - (ii) Built within the walls of the facility.

20 CAR § 43-151. Physical facilities — Imaging suite.

(a) General.

- (1) Equipment and space shall be as required by the functional program.
- (2)(A) A certified physicist or other qualified expert shall specify the type, location, and amount of radiation protection to be installed in accordance with the final approved department layout and equipment selections.
- (B) Where protected alcoves with view windows are required, a minimum of one foot six inches (1' 6") between the view window and the outside partition edge shall be provided.

(C) Radiation protection requirements shall be incorporated into the specifications and the building plans.

(3)(A) The State Radiation Control Agency and the Division of Emergency Management shall be notified when any existing and/or new equipment has been relocated or introduced into the facility.

(B) State Radiation Control Agency approval for the equipment and space or spaces shall be obtained prior to use.

(b) Angiography.

(1) Space shall be provided as required by the functional program.

(2)(A) A control room shall be provided as necessary to meet the needs of the functional program.

(B) A view window in the control room shall be provided to permit full view of the patient.

(3) A viewing area shall be provided.

(4) A scrub sink located outside the staff entry to the procedure room shall be provided for use by staff.

(5) A patient holding area shall be provided.

(6) Storage for portable equipment and supplies shall be provided.

(7) Provisions shall be made within the facility for extended postprocedure observation of outpatients.

(c) Computerized tomography (CT) scanning.

(1)(A) A control room shall be provided that is designed to accommodate the computer and other controls for the equipment.

(B) A view window shall be provided to permit full view of the patient.

(C) The angle between the control and equipment centroid shall permit the control operator to see the patient's head.

(2) The control room shall be located to allow convenient film processing.

(3) A patient toilet room shall be convenient to the procedure room, and if directly accessible to the scan room, arranged so that a patient may leave the toilet without having to reenter the scan room.

(d) Diagnostic X-ray, e.g., tomography, radiography/fluoroscopy rooms, mammography.

- (1) Radiology rooms shall be of a size to accommodate the functional program.
- (2) Each X-ray room shall include a shielded control alcove.
- (3) This area shall be provided with a view window designed to provide full view of the examination table and the patient at all times, including full view of the patient when the:
 - (A) Table is in the tilt position; or
 - (B) Chest X-ray is being utilized.
- (4) For mammography machines with built-in shielding for the operator, the alcove may be omitted when approved by the:
 - (A) Certified physicist; or
 - (B) State radiation protection agency.

(e) Magnetic resonance imaging (MRI).

- (1) Space shall be provided as required by the functional program.
- (2) A control room shall be provided with full view of the MRI.
- (3) A computer room shall be provided.
- (4) A patient holding area should be located near the MRI unit.
- (5) Cryogen venting shall comply with manufacturer's recommendations.

(f) Ultrasound.

- (1) Space shall be provided as required by the functional program.
- (2) A patient toilet room, accessible from the procedure room, shall be provided.

(g) Support spaces. The following spaces are common to the imaging department and are minimum requirements unless stated otherwise:

- (1)(A) Patient waiting area.
 - (B) The area shall have a seating capacity in accordance with the functional program;
- (2) Control desk and reception area;
- (3)(A) Holding area.

(B) A convenient holding area under staff control shall be provided to accommodate patients on stretchers or beds;

(4)(A) Patient toilet rooms.

(B) Toilet rooms shall be:

- (i) Provided convenient to the waiting rooms; and
- (ii) Equipped with an emergency call system.

(C) Separate toilets with handwashing stations shall be provided with direct access from each radiography/fluoroscopy room so that a patient may leave the toilet without having to reenter the radiography/fluoroscopy room.

(D) Rooms used only occasionally for fluoroscopy procedures may utilize nearby patient toilets if they are located for immediate access;

(5)(A) Patient dressing rooms.

(B) Dressing rooms shall be provided convenient to the waiting areas and X-ray rooms.

(C) Each room shall include:

- (i) A seat or bench;
- (ii) A mirror; and
- (iii) Provisions for hanging patients' clothing;

(6)(A) Staff facilities.

(B) Toilets may be outside the suite but shall be convenient for staff use.

(C) In larger suites of three (3) or more procedure rooms, toilets internal to the suite shall be provided;

(7)(A) Image storage.

(B) Provisions shall be provided by the facility for the active and inactive image storage.

(C) A room with cabinet or shelves for filing patient images for immediate retrieval shall be provided.

(D) A room or area for inactive image storage shall be provided.

(E) It may be outside the imaging suite, but shall be:

- (i) Under imaging's administrative control; and

- (ii) Properly secured to protect films against loss or damage;
- (8)(A) Storage for unexposed image.
 - (B) Storage facilities for unexposed images shall:
 - (i) Include protection of film against exposure or damage; and
 - (ii) Shall not be warmer than the air of adjacent occupied spaces;
- (9) Provisions for image viewing, individual consultation, clerical spaces, and charting shall be provided;
- (10)(A) Contrast media preparation.
 - (B) This area shall be provided with sink, counter, and storage to allow for mixing of contrast media.
 - (C) One (1) preparation area, if conveniently located, may serve any number of rooms.
 - (D) When prepared media is used, this area may be omitted, but storage shall be provided for the media;
- (11)(A) Image processing room.
 - (B) A darkroom shall be provided for image processing unless the processing equipment normally used does not require a darkroom for loading and transfer.
 - (C) When daylight processing is used, the darkroom may be minimal for emergency and special uses.
 - (D) Image processing shall be located convenient to the:
 - (i) Procedure rooms; and
 - (ii) Quality control area;
- (12)(A) Quality control area.
 - (B) An area shall be provided near the processor for viewing film immediately after it is processed.
 - (C) All view boxes shall be illuminated to provide light of the same color value and intensity for appropriate comparison of several adjacent images;
- (13)(A) Cleanup facilities.
 - (B) Provisions for cleanup shall:

- (i) Be located within the suite for convenient access and use; and
- (ii) Include service sink or floor receptacle as well as storage space for equipment and supplies.

(C) If automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning the processor racks shall be provided;

(14)(A) Handwashing stations.

(B) Handwashing stations shall be provided within each procedure room unless the room is used only for routine screening such as chest X-rays where the patient is not physically handled by the staff.

(C) Handwashing stations shall be provided convenient to the MRI room but need not be within the room;

(15)(A) Clean storage.

(B) Provisions shall be made for the storage of clean supplies and linens.

(C) If conveniently located, storage may be shared with another department;

(16)(A) Soiled holding.

(B) Provisions shall be made for soiled holding.

(C) Separate provisions for contaminated handling and holding shall be made.

(D) Handwashing stations shall be provided; and

(17) Provision shall be made for locked storage of medications and drugs.

(h) **Cardiac catheterization lab.**

(1) **Note.** The number of procedure rooms and the size of the prep, holding, and recovery areas shall be based on expected utilization.

(2)(A) The cardiac catheterization lab is normally a separate suite, but may be within the imaging suite when the appropriate sterile environment is provided.

(B) It may be combined with angiography in low usage situations.

(3) The procedure room shall be a minimum of four hundred square feet (400 sq. ft.) exclusive of fixed and movable cabinets and shelves.

(4)(A) A control room or area for the efficient functioning of the X-ray and image recording equipment.

(B) A view window permitting full view of the patient from the control console shall be provided.

(5) An equipment room or enclosure large enough to contain X-ray transformers, power modules, and associated electronics and electrical gear shall be provided.

(6) Scrub facilities with hands-free operable controls shall be:

(A) Provided adjacent to the entrance of procedure rooms; and

(B) Arranged to minimize incidental splatter on nearby:

(i) Personnel;

(ii) Medical equipment; or

(iii) Supplies.

(7) The following shall be available for use by the cardiac catheterization suite:

(A) A viewing room; and

(B) A film file room.

(8) Staff change area or areas shall be provided and arranged to ensure a traffic pattern so that personnel entering from outside the suite can:

(A) Enter;

(B) Change their clothing; and

(C) Move directly into the cardiac catheterization suite.

(9) A patient preparation, holding, and recovery area or room shall be provided and arranged to provide visual observation before and after the procedure.

(10)(A) A clean workroom or clean supply room shall be provided.

(B) If the room is used for preparing patient care items, it shall contain a work counter and handwashing sink.

(C) If the room is used only for storage and holding of clean and sterile supply materials, the work counter and handwashing stations may be omitted.

(11)(A) A soiled workroom shall be provided that shall contain a handwashing and a clinical sink or equivalent flushing-rim fixtures.

(B) When the room is used for temporary holding of soiled materials, the clinical sink may be omitted.

(12) A housekeeping closet containing a floor receptor or service sink and provisions for storage of supplies and housekeeping equipment shall be provided.

20 CAR § 43-152. Physical facilities — Nuclear medicine.

(a) Equipment and space shall be provided to accommodate the functional program.

(b)(1) A certified physicist or other qualified expert representing the owner shall specify the type, location, and amount of radiation protection to be installed in accordance with final approved department layout and equipment selection.

(2) These specifications shall be incorporated into the plans.

(c) Floors and walls shall be constructed of materials that are easily decontaminated in case of radioactive spills.

(d)(1) If radiopharmaceutical preparation is performed onsite, an area adequate to house a radiopharmacy shall be provided with appropriate shielding.

(2) This area should include:

- (A) Adequate space for storage of radionuclides;
- (B) Chemicals for preparation;
- (C) Dose calibrators; and
- (D) Recordkeeping.

(3) Floors and walls should be constructed of easily decontaminated materials.

(4) Vents and traps for radioactive gases should be provided if such are used.

(5) Hoods for pharmaceutical preparation shall meet applicable standards.

(6) If preprepared materials are used, storage and calculation area may be considerably smaller than that for onsite preparation.

(7) Space shall provide adequately for:

- (A) Dose calibration;
- (B) Quality assurance; and
- (C) Recordkeeping.

(8) This area may still require shielding from other portions of the facilities.

(e) Nuclear medicine area when operated separately from the imaging department shall include the following as required to accommodate the functional program:

(1) Space adequate to:

(A) Permit entry of stretchers and beds; and

(B) Be able to accommodate:

(i) Imaging equipment;

(ii) Electronic consoles; and

(iii) If present, computer terminals;

(2)(A) A darkroom onsite available for film processing.

(B) The darkroom should contain protective storage facilities for unexposed film that guard the film against exposure or damage;

(3) When the functional program requires a centralized computer area, it should be a separate room with access terminals available within the imaging rooms;

(4)(A) Provisions for cleanup located within the suite for convenient access and use.

(B) It shall include service sink or floor receptacle as well as storage space for equipment and supplies;

(5) Film storage with cabinets or shelves for filing patient film for immediate retrieval;

(6) Inactive film storage:

(A) Under the departmental administrative control; and

(B) Properly secured to protect film against loss or damage;

(7) A consultation area with view boxes illuminated to provide light of the same color value and intensity for appropriate comparison of several adjacent films;

(8) Provisions for:

(A) Physicians;

(B) Assistants;

(C) Clerical office space;

(D) Individual consultation;

- (E) Viewing; and
- (F) Charting of film;
- (9)(A) Waiting areas:
 - (i) Out of traffic;
 - (ii) Under staff control; and
 - (iii) With seating capacity in accordance with the functional program.
- (B) If the department is routinely used for outpatients and inpatients at the same time, separate waiting areas with screening or visual privacy between the waiting areas;
- (10) A private area for dose administration located near the preparation area;
- (11) A holding area for patients on stretchers or beds that may be provided and may be combined with the dose administration area with visual privacy between the areas;
- (12)(A) Patient dressing rooms convenient to the waiting area and procedure rooms.
 - (B) Each dressing room shall include:
 - (i) A seat or bench;
 - (ii) A mirror; and
 - (iii) Provisions for hanging patient's clothing;
- (13) Toilet rooms convenient to waiting and procedure rooms;
- (14) Staff toilet or toilets convenient to the nuclear medicine laboratory;
- (15) Handwashing stations within each procedure room;
- (16) Control desk and reception area;
- (17) Storage area for clean linen with a handwashing station;
- (18)(A) Provisions shall be made for holding soiled material.
 - (B) Such provision shall include a handwashing station; and
- (19) Separate provision shall be made for holding contaminated material exposed to radiation.
- (f) **Positron emission tomography (PET).**

(1) Space should be provided as necessary to accommodate the functional program.

(2)(A) PET scanning:

(i) Is generally used in experimental settings; and

(ii) Requires space for a scanner and for a cyclotron.

(B) The scanner room should be a minimum of three hundred square feet (300 sq. ft.).

(3) Where a cyclotron room is required, it should be a minimum of two hundred twenty-five square feet (225 sq. ft.) with a sixteen-square-foot space safe for storage of parts that may need to cool down for a year or more.

(4) Both a hot (radioactive) lab and a cold (nonradioactive) lab may be required, each a minimum of two hundred fifty square feet (250 sq. ft.).

(5) A blood lab of a minimum of eighty square feet (80 sq. ft.) should be provided.

(6) A patient holding area to accommodate two (2) stretchers should be provided.

(7)(A) A gas storage area large enough to accommodate bottles of gas should be provided.

(B) Each gas:

(i) Will be piped individually; and

(ii) May go to the cyclotron or to the lab.

(C) Ventilation adequate for the occupancy is required.

(D) Compressed air may be required to pressurize a water circulation system.

(8) Significant radiation protection may be required since the cyclotron may generate high radiation.

(9) Special ventilation systems together with monitors, sensors, and alarm systems may be required to vent gases and chemicals.

(10)(A) The heating, ventilating, and air conditioning system will require particular attention:

- (i) Highest pressures should be in coldest (radiation) areas; and
- (ii) Exhaust should be in hottest (radiation) areas.

(B) Redundancy may be important.

(11)(A) The cyclotron is water-cooled with deionized water.

(B) A heat exchanger and connection to a compressor or connection to chilled water may be required.

(C) A redundant plumbing system connected to a holding tank may be required to prevent accidental leakage of contaminated water into the regular plumbing system.

(g) **Radiotherapy.**

(1)(A) Rooms and spaces shall be provided as required by the functional program.

(B) Equipment manufacturers' recommendations should be sought and followed since space requirements may vary from:

- (i) One (1) machine to another; and
- (ii) One (1) manufacturer to another.

(C) The radiotherapy suite may contain one (1) or both:

- (i) Electron beam therapy; and
- (ii) Radiation therapy.

(2)(A) Cobalt, linear accelerators, and simulation rooms require radiation protection.

(B) A certified physicist representing the owner or appropriate state agency shall specify the type, location, and amount of protection to be installed in accordance with final approved department layout and equipment selection.

(C) This information shall be incorporated into the floor plans.

(3)(A) Cobalt rooms and linear accelerators shall:

- (i) Be sized in accordance with equipment requirements; and
- (ii) Accommodate a stretcher for litter-borne patients.

(B) Layouts shall provide for preventing the escape of radioactive particles.

(C) Openings into the room including doors, ductwork, vents, and electrical raceways and conduits shall be baffled to prevent direct exposure to other areas of the facility.

(4) Simulator, accelerator, and cobalt rooms shall be sized to accommodate the equipment with:

- (A) Patient access on a stretcher;
- (B) Medical staff access to the equipment and patient; and
- (C) Service access.

(5)(A) Flooring shall be adequate to meet load requirements for:

- (i) Equipment;
- (ii) Patients; and
- (iii) Personnel.

(B) Provision for wiring raceways, ducts, or conduit should be made in floors and ceilings.

(C) Ceiling-mounted equipment should have properly designed rigid support structures located above the finished ceiling.

(D) The ceiling height is normally higher than eight feet (8') or two and forty-four hundredths meters (2.44 m).

(E) A lay-in type of ceiling should be considered for ease of:

- (i) Installation;
- (ii) Service; and
- (iii) Remodeling.

(6)(A) Additional support areas for linear accelerator:

- (i) Mold room with exhaust hood and handwashing facility; and
- (ii) Block room with storage.

(B) The block room may be combined with the mold room.

(7) Additional support areas for cobalt room.

(h) **General support areas.** The following areas shall be provided unless they are accessible from other areas such as imaging:

(1) A stretcher holding area adjacent to the treatment rooms, screened for privacy, that may be combined with a seating area for outpatients;

(2)(A) Exam rooms as specified by the functional program.

(B) Each shall be:

(i) A minimum of one hundred twenty square feet (120 sq. ft.); and

(ii) Equipped with a handwashing station;

(3)(A) Darkroom convenient to the:

(i) Treatment room or rooms; and

(ii) Quality control area.

(B) Where daylight processing is used, the darkroom may be minimal for emergency use.

(C) If automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning the processor racks shall be provided either in the darkroom or nearby;

(4)(A) Patient gowning area with provision for safe storage of valuables and clothing.

(B) At least one (1) space should be large enough for staff-assisted dressing;

(5) Business office and/or reception/control area;

(6) Housekeeping room:

(A) Equipped with service sink or floor receptor; and

(B) Large enough for equipment or supplies storage;

(7) Image file area; and

(8) A storage area for unprocessed media.

(i) **Optional support area.** The following areas may be required by the functional program:

(1) Quality control area with view boxes illuminated to provide light of the same color value and intensity;

(2) Computer control area normally located just outside the entry to the treatment room or rooms;

- (3) Dosimetry equipment area;
- (4) Hypothermia room (may be combined with an exam room);
- (5) Consultation room;
- (6) Oncologist's office (may be combined with consultation room);
- (7) Physicist's office (may be combined with treatment planning);
- (8) Treatment planning and record room; and
- (9) Workstation or / nutrition station.

20 CAR § 43-153. Physical facilities — Mobile, transportable, and relocatable units.

(a) **General.** This section applies to mobile, transportable, and relocatable structures.

(b) **Definitions.** As used in this section:

(1) "Mobile unit" means any premanufactured structure, trailer, or self-propelled unit:

- (A) Equipped with a chassis on wheels; and
- (B) Intended to provide medical services on a temporary basis;

(2) "Relocatable unit" means any structure not on wheels built to:

- (A) Be relocated at any time; and
- (B) Provide medical services; and

(3) "Transportable unit" means any premanufactured structure or trailer equipped with a chassis on wheels intended to provide medical services on an extended basis.

(c) **General considerations.**

(1) **Classifications.** These facilities shall be classified as either a small outpatient facility, large outpatient facility, ambulatory surgery center, or a hospital based upon the definitions provided in the rules, the program functional and construction type.

(2) **Applicable requirements.**

(A) Facilities classified as a small outpatient clinic shall be designed in accordance with the requirements stipulated in 20 CAR § 43-174, physical facilities — outpatient care facilities.

(B) Facilities classified as a large outpatient facility shall be designed in accordance with the requirements stipulated in 20 CAR § 43-174(f), physical facilities — outpatient care facilities.

(C) Facilities classified as a hospital shall be designed in accordance with the requirements stipulated in 20 CAR § 43-142, physical facilities.

(3) These requirements shall be applicable to mobile, transportable, and relocatable structures when such structures are used to provide shared medical services on an extended or a temporary basis.

(4) When any mobile unit, transportable, and relocatable unit or units are situated in a fixed location and rendered immobile they shall be classified and designed as a healthcare facility.

(d) Common elements for mobile, transportable, and relocatable units.

Site conditions:

(1)(A) Access for the unit to arrive shall be taken into consideration for space planning.

(B) Turning radius of the vehicles, slopes of the approach (six percent (6%) maximum), and existing conditions shall be addressed;

(2)(A) Gauss fields of various strengths of magnetic resonance imaging (MRI) units shall be considered for the environmental effect on the field homogeneity and vice-versa.

(B) Radio frequency interference shall be considered when planning the site;

(3) Sites shall be provided with properly sized power, including emergency power, water, waste, telephone, and fire alarm connections;

(4) Site shall:

(A) Have level concrete pads or piers; and

(B) Be designed for the structural loads of the facility;

(5)(A) Sites utilizing MRI systems shall consider providing adequate access for cryogen servicing of the magnet.

(B) Storage of dewars also shall be included in space planning;

(6) It is recommended that each site provide a covered walkway or enclosure to ensure patient safety from the outside elements;

(7) Diesel exhaust of the tractor and/or unit generator shall be twenty-five feet (25') away from the fresh air intake of the facility;

(8) Each facility shall provide a means of preventing unit movement, either by:

(A) Blocking the wheels; or

(B) Providing pad anchors;

(9) Sites shall provide:

(A) Hazard-free patient drop-off zones; and

(B) Adequate parking;

(10) The facility shall provide waiting space for patient privacy and patient and staff toilets as close to the unit docking area as possible;

(11) Each site shall provide access to the unit for wheelchair/stretchers patients; and

(12)(A) Mobile units shall be provided with handwashing stations unless each site can provide handwashing stations within a twenty-five-foot proximity to the unit.

(B) Transportable and relocatable units shall be provided with handwashing stations.

(e) General standards for details and finishes for unit construction.

(1) Horizontal sliding doors and power-operated doors shall comply with NFPA 101.

(2) Units shall be permitted a single means of egress as permitted by NFPA 101.

(3) All glazing in doors shall be safety or wired glass.

(4)(A) Units shall be equipped with fire detection and alarm systems.

(B) In relocatable and transportable units, these systems shall be connected to the central fire alarm system.

(5) Radiation protection for X-ray and gamma ray installations shall be in accordance with Rules for Control of Sources of Ionizing Radiation, 20 CAR pt. 3.

(6) Interior finish materials shall be Class A as defined in NFPA 101.

(7) Textile materials having a napped, tufted, looped, woven, nonwoven, or similar surface shall be permitted on walls and ceilings provided:

(A) Such materials have a Class A rating; and

(B) Rooms or areas are protected by an automatic extinguishment or sprinkler system.

(8) Fire retardant coatings shall be permitted in accordance with NFPA 101.

(9) Curtains and draperies shall:

(A) Be noncombustible or flame retardant; and

(B) Pass both the large-scale and small-scale tests required by NFPA 101.

(10) Fire retardant coatings shall be permitted in accordance with NFPA 101.

(f) Mechanical standards.

(1) Air conditioning, heating, ventilating, ductwork, and related equipment shall be installed in accordance with NFPA 90A: Standard for the Installation of Air Conditioning and Ventilation Systems.

(2) Plumbing standards.

(A) Plumbing and other piping systems shall be installed in accordance with the Arkansas Plumbing Code, 17 CAR pt. 65.

(B)(i) Mobile units requiring sinks shall not be required to be vented through the roof.

(ii) Ventilation of waste lines shall be permitted to be vented through:

(a) The sidewalls; or

(b) Other acceptable locations.

(iii) Transportable and relocatable units shall be vented through the roof per model plumbing codes.

(C) Backflow prevention shall be installed at the point of water connection on the unit.

(D) Medical gases and suction systems, if installed, shall be in accordance with NFPA 99.

(g) Electrical standards.

(1) All electrical material and equipment, including conductors, controls, and signaling devices, shall be:

(A) Installed in compliance with applicable sections of NFPA 70 and NFPA 99; and

(B) Shall be listed as complying with available standards of listing agencies or other similar established standards where such standards are required.

(2)(A) The electrical installations, including alarm, nurse call, and communication systems, shall be tested to demonstrate that equipment installation and operation is appropriate and functional.

(B) A written record of performance tests on special electrical systems and equipment shall show compliance with applicable codes and standards.

(3) Data processing and/or automated laboratory or diagnostic equipment, if provided, may require safeguards from power line disturbances.

(4)(A) Main switchboards shall be:

(i) Located in an area separate from plumbing and mechanical equipment; and

(ii) Accessible to authorized persons only.

(B) Switchboards shall be:

(i) Convenient for use;

(ii) Readily accessible for maintenance;

(iii) Away from traffic lanes; and

(iv) Located in dry, ventilated spaces free of:

(a) Corrosive or explosive fumes and gases; or

(b) Any flammable material.

(C) Overload protective devices shall operate properly in ambient room temperatures.

(5) Panelboards serving normal lighting and appliance circuits shall be located on the same level as the circuits they serve.

(6) Lighting shall be engineered to the specific application.

(7)(A) The Illuminating Engineering Society (IES) has developed recommended lighting levels for healthcare facilities.

(B) The reader should refer to the IES Lighting Handbook (1993).

(8) Approaches to buildings and parking lots and all occupied spaces shall have fixtures for lighting that can be illuminated as necessary.

(9)(A) Consideration should be given to the special needs of the elderly.

(B) Excessive contrast in lighting levels that make effective sight adaptation difficult should be minimized.

(10) A portable or fixed examination light shall be provided for examination, treatment, and trauma rooms.

(11)(A) Duplex grounded-type receptacles (convenience outlets) shall be installed in all areas in sufficient quantities for tasks to be performed as needed.

(B) Each examination and worktable shall have access to a minimum of two (2) duplex receptacles.

(12) At inhalation anesthetizing locations, all electrical equipment and devices, receptacles, and wiring shall comply with applicable sections of NFPA 99 and NFPA 70.

(13) Fixed and mobile X-ray equipment installations shall conform to Articles 517 and 660 of NFPA 70.

(14) Emergency lighting and power shall be provided for in accordance with NFPA 99, NFPA 101, and NFPA 110.

(15) The fire alarm system shall be as described in NFPA 101 and, where applicable, NFPA 72.

(16)(A) Terminating devices for telecommunications and information systems wiring shall be located on the unit that the terminating devices serve.

(B) These terminating devices shall be accessible to authorized personnel only.

(17) Special air conditioning and voltage regulation shall be provided when recommended by the manufacturer.

20 CAR § 43-154. Physical facilities — Laboratory services.

(a)(1) Facilities necessary for providing laboratory services described in the narrative program shall be provided.

(2)(A) The laboratory shall be constructed, arranged, and maintained to ensure adequate space, ventilation, and utilities necessary for conducting all phases required of testing in accordance with current Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, regulations.

(B) Refer to 20 CAR § 43-118.

(b)(1) Specimen collection facilities shall be provided.

(2) These facilities may be located outside the laboratory suite.

(3) The blood collection area shall have:

(A) A work counter;

(B) Space for patient seating; and

(C) Handwashing facilities.

(4) Urine and feces collection room or rooms shall be equipped with a water closet and a lavatory.

(c)(1) Provisions shall be made for safety from physical, chemical, and biological hazards.

(2) There shall be eye flushing devices, appropriate storage of flammable liquids, emergency spill kit or kits, and fire extinguishers as required by NFPA 99.

(d) Locker and toilet facilities for laboratory staff shall be located convenient to the laboratory area.

20 CAR § 43-155. Physical facilities — Rehabilitation therapy department.

(a) **Common elements.** Each rehabilitative therapy department shall include the following that may be shared or provided as separate units for each service:

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(1) Office and clerical space with provisions for filing and retrieval of patient records;

(2)(A) Reception and control station or stations with visual control of waiting and activities area.

(B) This may be combined with office and clerical space;

(3) Patient waiting area or areas out of traffic with provision for wheelchair patients;

(4) Patient toilets with handwashing stations accessible to wheelchair patients;

(5)(A) A space or spaces for storing wheelchairs and stretchers out of traffic while patients are using the services.

(B) These spaces may be separate from the service area but shall be conveniently located;

(6) A conveniently accessible housekeeping room and service sink for housekeeping use;

(7) Locking closets or cabinets within the vicinity of each work area for securing staff personal effects;

(8) Convenient access to toilets and lockers;

(9) Access to a demonstration/conference room; and

(10) Lockable storage for medications.

(b) **Physical therapy.** If physical therapy is part of the service, the following at least shall be included:

(1)(A) Individual treatment area or areas with privacy screens or curtains.

(B) Each such space shall have not less than seventy square feet (70 sq. ft.) of clear floor area;

(2)(A) Handwashing stations for staff either within or at each treatment space.

(B) One (1) handwashing station may serve several stations;

(3) Exercise area and facilities;

(4) Clean linen and towel storage;

(5) Storage for equipment and supplies;

(6) Separate storage for soiled items; and

(7) Patient change area if required by the functional program.

(c) **Occupational therapy.** If this service is provided, at least the following shall be included:

- (1) Work areas and counters suitable for wheelchair access;
- (2) Handwashing stations;
- (3) Storage for supplies and equipment; and
- (4)(A) An area for daily living activities shall be provided.
 - (B) It shall contain an area for a:
 - (i) Bed;
 - (ii) Kitchen counter with appliances and sink;
 - (iii) Bathroom; and
 - (iv) Table/chair.

(d) **Prosthetics and orthotics.** If this service is provided, at least the following shall be included:

- (1) Workspace for technicians;
- (2) Space for evaluating and fitting with provisions for privacy; and
- (3) Space for:
 - (A) Equipment;
 - (B) Supplies; and
 - (C) Storage.

(e) **Recreation therapy.**

(1) **Note.**

(A) Recreation therapy assists patients in the development and maintenance of community living skills through the use of leisure-time activity tasks.

(B) These activities may occur:

- (i) In a recreation therapy department;
- (ii) In specialized facilities (e.g., gymnasium);
- (iii) In a multipurpose space in other areas (e.g., the nursing unit); or
- (iv) Outdoors.

(2) If this service is provided, at least the following shall be included:

- (A) Activity areas suitable for wheelchair access;
 - (B) Handwashing stations if required by the program;
 - (C) Storage for supplies and equipment;
 - (D) Secured storage for supplies and equipment that are potentially harmful; and
 - (E) Remote electrical switching for equipment that is potentially harmful.
- (f) **Speech, hearing, and audio therapy.** If this service is provided, at least the following shall be included:
- (1)(A) Space for evaluation and treatment of patients.
 - (B) The space shall be protected with acoustical treatment of walls and finishes; and
 - (2) Space for equipment storage and supplies.
- (g) **Respiratory care.** If respiratory care is part of the service, the following at least shall be included as a minimum:
- (1)(A) Storage of equipment and supplies.
 - (B)(i) Space and utilities for cleaning and sanitizing equipment.
 - (ii) Provide physical separation of the space for receiving and cleaning soiled materials from the space for storage of clean equipment and supplies.
 - (iii) Appropriate local exhaust ventilation shall be provided if glutaraldehyde or other noxious disinfectants are used in the cleaning.
 - (C) If respiratory services such as testing and demonstration for outpatients are part of the program, additional facilities and equipment shall be provided as necessary for the appropriate function of the service, including but not limited to:
 - (i) Patient waiting area with provision for wheelchairs;
 - (ii) Reception and control station;
 - (iii) Patient toilets and handwashing facilities; and
 - (iv) A room or rooms for patient education and demonstration; and
 - (2)(A) Cough-inducing and aerosol-generating procedures.

(B) All cough-inducing procedures performed on patients who may have suspected or active infectious Mycobacterium tuberculosis shall be performed in rooms that meets the requirements for airborne infection control.

20 CAR § 43-156. Physical facilities — Morgue and necropsy.

(a) These facilities shall be:

- (1) Directly accessible to an outside entrance; and
- (2) Located to avoid movement of bodies through public areas.

(b) The following elements shall be provided when autopsies are performed within the hospital:

(1) Refrigerated facilities for body-holding; and

(2)(A) Autopsy room.

(B) This room shall contain:

- (i) Work counter with sink equipped for handwashing;
- (ii) Storage space for supplies, equipment, and specimens;
- (iii) Autopsy table;
- (iv) A deep sink for washing of specimens; and
- (v) A housekeeping service sink or receptor for cleanup and

housekeeping.

(C) **Note.** If autopsies are performed outside the facility, only a well-ventilated, temperature-controlled, body-holding room need be provided.

20 CAR § 43-157. Physical facilities — Pharmacy.

(a)(1) The size and type of services to be provided in the pharmacy can largely depend upon the:

- (A) Type of medication distribution system used;
- (B) Number of patients to be served; and
- (C) Extent of shared or purchased services.

(2) This shall be described in the functional program.

(b) The pharmacy room or suite shall be located for:

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- (1) Convenient access;
- (2) Staff control; and
- (3) Security.

(c)(1) Facilities and equipment shall be as necessary to accommodate the functions of the program.

(2) See 20 CAR § 43-115, pharmacy, for additional requirements.

(3) Satellite facilities, if provided, shall include those items required by the program.

(d) As a minimum, the following elements shall be included:

(1)(A) Dispensing.

(B) A pickup and receiving area.

(C) An area for reviewing and recording.

(D) An extemporaneous compounding area that includes:

(i) A sink; and

(ii) Sufficient counter space for medication preparation.

(E) Work counters and space for automated and manual dispensing activities.

(F) An area for temporary storage, exchange, and restocking of carts.

(G) Security provisions for medications and personnel in the dispensing counter area;

(2)(A) Manufacturing.

(B) A bulk compounding area.

(C) Provisions for packaging and labeling.

(D) A quality control area;

(3)(A) Storage — May be cabinets, shelves, and/or separate rooms or closets.

(B) Bulk storage.

(C) Active storage.

(D) Refrigerated storage.

(E) Volatile fluids and alcohol storage constructed according to applicable fire safety codes for the substances involved.

- (F) Double-locked storage for controlled substances.
- (G) Storage for general supplies and equipment not in use;
- (4)(A) Administration.
 - (B)(i) An area for education and training.
 - (ii) May be in a multipurpose room shared with other departments.
 - (C)(i) An area for patient counseling and instruction.
 - (ii) May be in a room separate from the pharmacy.
 - (D) A separate area for office functions; and
- (5)(A) Other.
 - (B) Handwashing stations shall be provided within each separate room where open medication is handled and readily accessible.
 - (C) Provide for convenient access to toilet and locker.
 - (D) If unit dose procedure is used, provide additional space and equipment for supplies, packaging, labeling, and storage, as well as for the carts.
 - (E)(i) If IV solutions are prepared in the pharmacy, provide a sterile work area with a laminar flow workstation designed for product protection.
 - (ii) The laminar-flow system shall:
 - (a) Include a nonhygroscopic filter (HEPA) rated at ninety-nine and ninety-seven hundredths percent (99.97%) as tested by DOP tests; and
 - (b) Have a visible pressure gauge for detection of filter leaks or defects.
 - (F) Hoods used for chemotherapy shall be one hundred percent (100%) exhausted to the exterior.
 - (G) As a minimum, the partitions enclosing the pharmacy shall extend from the floor to the deck above with gypsum board on both sides of metal studs.

20 CAR § 43-158. Physical facilities — Dietary facilities.

- (a) Construction, equipment, and installation shall comply with the standards specified in Food and Drug Administration Food Code.

(b) Food service facilities shall be designed and equipped to meet the requirements of the functional program.

(c) These may consist of:

- (1) An onsite conventional food preparing system;
- (2) A convenience food service system; or
- (3) An appropriate combination of the two (2).

(d) The following shall be provided:

(1)(A) Receiving/control area.

(B) Provide an area for the receiving and control of incoming dietary supplies.

(C) This area shall be separated from the general receiving area and shall contain the following:

- (i) A control station; and
- (ii) A breakout for loading, uncrating, and weighing supplies;

(2)(A) Storage spaces.

(B)(i) A minimum of four (4) days' supplies shall be stocked.

(ii) In remote areas, this number may be increased to accommodate length of delivery in emergencies.

(C) All food shall be stored clear of the floor.

(D) Lowest shelf shall:

- (i) Not be less than twelve inches (12") above the floor; or
- (ii) Be closed in and sealed tight for ease of cleaning;

(3)(A) Cleaning supplies storage.

(B) Provide a separate storage room for the storage of nonfood items such as cleaning supplies that might contaminate edibles;

(4)(A) Food preparation facilities.

(B) Conventional food preparation systems shall have adequate space and equipment for:

- (i) Preparing;
- (ii) Cooking; and

(iii) Baking.

(C) Convenience food preparation systems shall have adequate space for equipment for:

(i) Thawing;

(ii) Portioning;

(iii) Cooking; and/or

(iv) Baking.

(D) These areas shall be as close as possible to the user (i.e., tray assembly and dining);

(5)(A) Assembly and distribution areas.

(B) A patient tray assembly area shall be located within close proximity to the food preparation and distribution areas;

(6)(A) Food service carts.

(B) A cart distribution area shall provide space for storage, loading, distribution, receiving, and sanitizing of food service carts.

(C) The cart traffic shall be designed to eliminate any danger of cross-circulation between outgoing food carts and incoming, soiled carts, and the cleaning and sanitizing process.

(D) Cart circulation shall not traffic through food processing areas;

(7)(A) Handwashing stations.

(B) These shall be:

(i) Operable without the use of hands; and

(ii) Readily accessible at locations throughout the dietary department;

(8)(A) Dining area.

(B) There shall be dining space for ambulatory patients, staff, and visitors that is separate from the food preparation and distribution areas;

(9)(A) Area for receiving, scraping, and sorting soiled tableware.

(B) Area shall be:

(i) Adjacent to ware washing; and

(ii) Separate from food preparation areas.

- (C) A handwashing fixture shall be conveniently available;
- (10)(A) Dishwashing space.
 - (B) An area shall be located in a room separate from food preparation and serving areas.
 - (C) Commercial-type dishwashing equipment shall be provided.
 - (D) Clean and soiled dish areas shall be separated with an opening in the partition between the clean and soiled dish area large enough for:
 - (i) The dishwasher; and
 - (ii) Ventilation of the area.
 - (E) The clean dish area may be either a:
 - (i) Separate room; or
 - (ii) Portion of the kitchen.
 - (F) A lavatory shall be conveniently available.
 - (G) The soiled dish area shall be so located as to prevent soiled dishes from being carried through the food preparation area;
- (11)(A) Ware washing facilities.
 - (B) They shall be designed to prevent contamination of clean wares with soiled wares through cross-traffic.
 - (C) The clean wares should be transferred for storage or use in the dining area without having to pass through food preparation areas;
- (12)(A) Pot washing facilities including multicompartmented sinks of adequate size for intended use shall be provided convenient to using service.
 - (B) Supplemental heat for hot water to clean pots and pans may be by booster heater or by steam jet;
- (13)(A) Waste storage room.
 - (B) A food waste storage room shall be conveniently located to the food preparation and ware washing areas but not within the food preparation area.
 - (C) It shall have direct access to the hospital's waste collection and disposal facilities;
- (14)(A) Storage rooms and areas.

(B) A room for cans, carts, mobile tray conveyors, and cleaning and sanitizing carts shall be provided.

(C) There shall be a separate storage room for the storage of nonfood items that might contaminate edibles (i.e., cleaning supplies).

(D) A separate space or room for the storage of cooking wares, extra trays, flatware, plastic and paper products, and portable equipment is required;

(15)(A) Toilets and locker spaces.

(B) Lockers, if provided in the dietary facility, shall be for the exclusive use of the dietary staff.

(C) Toilets and lockers shall not open directly into the food preparation areas but shall be in close proximity to them;

(16)(A) Office or offices.

(B) Dietary service manager/supervisor offices shall be conveniently located for visual control of:

(i) Receiving area; and

(ii) Food preparation areas;

(17)(A) Environmental closet.

(B) A closet shall be provided for the exclusive use of the dietary department to contain:

(i) A floor sink; and

(ii) Space for:

(a) Mops;

(b) Pails; and

(c) Supplies.

(C) Where hot water or steam is used for general cleaning, additional space within the room shall be provided for the storage of hoses and nozzles;

(18)(A) Icemaking equipment.

(B) Equipment shall be:

(i) Convenient for service; and

(ii) Easily cleaned.

- (C) It shall be provided for both:
 - (i) Drinks (self-dispensing equipment); and
 - (ii) General use (storage-bin type equipment);
- (19)(A) Commissary or contract services from other areas.
- (B) If a service is used, above items may be reduced as appropriate.
- (C) The process of food delivery shall ensure:
 - (i) Freshness;
 - (ii) Retention of hot and cold; and
 - (iii) Avoidance of contamination.
- (D) If delivery is from outside sources, protection against weather shall be provided.
- (E) Provisions shall be made for thorough cleaning and sanitizing of equipment to avoid mix of soiled and clean equipment; and
- (20)(A) Equipment.
- (B) Mechanical devices shall be:
 - (i) Heavy duty;
 - (ii) Suitable for intended use; and
 - (iii) Easily cleaned.
- (C) Movable equipment shall have heavy-duty locking casters.
- (D) If equipment is to have fixed utility connections, it shall not be equipped with casters.
- (E) Walk-in coolers, refrigerators, and freezers shall be insulated at:
 - (i) Floor;
 - (ii) Walls; and
 - (iii) Top.
- (F) Coolers and refrigerators shall be capable of maintaining a temperature down to freezing.
- (G) Freezers shall be capable of maintaining a temperature of twenty degrees below zero Fahrenheit (-20°F).

(H) Coolers, refrigerators, and freezers shall be thermostatically controlled to maintain desired temperature settings in increments of two degrees (2°) or less.

(I) Interior temperatures shall be visible from the exterior.

(J) Controls may include audible and visible high and low temperature alarm.

(K) Time of alarm shall be automatically recorded.

(L) Walk-in units may be lockable from outside but shall have a release mechanism for exit from inside at all times.

(M) Interior shall be lighted.

(N) All shelving shall be:

(i) Corrosion resistant;

(ii) Easily cleaned; and

(iii) Constructed and anchored to support a loading of at least one hundred pounds (100 lb.) per linear foot.

(O) All cooking equipment shall be equipped with automatic shutoff devices to prevent excessive heat buildup.

(P) Under-counter conduits, piping, and drains shall be arranged to not interfere with cleaning of floor below or of the equipment.

20 CAR § 43-159. Physical facilities — Administration and public areas.

The following areas shall be provided:

(1) Facility entrance at grade level:

(A) Sheltered from the weather; and

(B) Able to accommodate wheelchairs;

(2) Lobby, that shall include:

(A) Reception and information counter or desk;

(B) Waiting space or spaces;

(C) Public toilet facilities one (1) for each sex;

(D) Public telephone or telephones; and

(E) Drinking fountain or fountains;

- (3) Interview space or spaces for private interviews relating to:
 - (A) Social service;
 - (B) Credit; and
 - (C) Admissions;
- (4) General or individual office or offices for:
 - (A) Business transactions;
 - (B) Medical and financial records; and
 - (C) Administrative and professional staffs;
- (5)(A) Multipurpose room or rooms with provisions for the use of visual aids for:
 - (i) Conferences;
 - (ii) Meetings; and
 - (iii) Health education.
- (B) One (1) multipurpose room may be shared by several services;
- (6) Storage for office equipment and supplies; and
- (7) Staff toilet facilities.

20 CAR § 43-160. Physical facilities — Health information unit.

- (a) The following rooms and areas shall be provided:
 - (1) Health information director's office or space;
 - (2) Review and dictating room or rooms or spaces;
 - (3) Work area for sorting, recording, or microfilming records; and
 - (4)(A) Medical record storage.
 - (B) Refer to 20 CAR § 43-167(b)(25).
- (b)(1) Rooms for patient medical records and archived patient medical records that remain onsite shall be:
 - (A) Kept in a one-hour fire-rated enclosure or protected by a sprinkler system; and
 - (B) Protected by a security system and a smoke detection system.

(2) Circulating records at the nurses' station or in active working areas are excluded from this requirement.

(3) The records shall be protected against undue destruction from dust, vermin, water, etc.

20 CAR § 43-161. Physical facilities — Central medical and surgical supply department.

The following areas shall be provided.

(1)(A) Separate soiled and clean work areas.

(B)(i) Soiled workroom.

(ii) This room shall be physically separated from all other areas of the department.

(iii) Workspace shall be provided to handle the cleaning and initial sterilization/disinfection of all:

(a) Medical/surgical instruments and equipment;

(b) Worktables;

(c) Sinks;

(d) Flush-type devices; and

(e) Washer/sterilizer decontaminators.

(iv) Pass-through doors and washer/sterilizer decontaminators shall deliver into clean processing area/workrooms.

(C)(i) Clean assembly/workroom.

(ii) This workroom shall contain handwashing stations, workspace, and equipment for terminal sterilizing of medical and surgical equipment and supplies.

(iii) Clean and soiled work areas shall be physically separated;

(2)(A) Storage areas.

(B) **Clean/sterile medical/surgical supplies.**

(i) A room shall be provided for the breakdown of clean/sterile bulk supplies.

(ii) Storage for packs etc., shall include provisions for:

- (a) Ventilation;
- (b) Humidity; and
- (c) Temperature control;

(3)(A) Administrative/changing room.

(B) If required by the functional program, this room shall:

- (i) Be separate from all other areas; and
- (ii) Provide for staff to change from street clothes into work attire.

(C) Lockers, sink, and showers shall be made available within the immediate vicinity of the department; and

(4)(A) Storage room for patient care and distribution carts.

(B) This area shall be adjacent, easily available to clean and sterile storage, and close to main distribution point to:

- (i) Keep traffic to a minimum; and
- (ii) Ease work flow.

20 CAR § 43-162. Physical facilities — Central supply and receiving.

(a) In addition to supply facilities in individual departments, a central storage area shall also be provided.

(b) General stores may be located in a separate building onsite with provisions for protection against inclement weather during transfer of supplies.

(c) The following shall be provided:

- (1) Off-street unloading facilities;
- (2) Receiving area;
- (3)(A) General storage room or rooms.

(B) General storage room or rooms with a total area of not less than twenty feet (20') per inpatient bed shall be provided.

(C) Storage may be in:

- (i) Separate, concentrated areas within the institution; or
- (ii) One (1) or more individual buildings onsite.

(D) A portion of this storage may be provided offsite; and

(4)(A) Additional storage room or rooms.

(B) Additional storage areas for outpatient facilities shall be provided in an amount not less than five percent (5%) of the total area of the outpatient facilities.

(C) This may be:

(i) Combined with and in addition to the general stores; or

(ii) Located in a central area within the outpatient department.

(D) A portion of this storage may be provided offsite.

20 CAR § 43-163. Physical facilities — Linen services.

(a)(1) Each facility shall have provisions for storing and processing of clean and soiled linen for appropriate patient care.

(2) Processing may be done:

(A) Within the facility;

(B) In a separate building onsite or offsite; or

(C) In a commercial or shared laundry.

(b) Facility processing.

(1) Facilities and equipment shall be as required for cost-effective operation as described in the functional program.

(2) At a minimum, the following elements shall be included:

(A) A separate room for receiving and holding soiled linen until ready for pickup or processing;

(B) A central, clean linen storage and issuing room or rooms, in addition to the linen storage required at individual patient units;

(C) Cart storage area or areas for separate parking of clean-linen and soiled-linen carts out of traffic;

(D)(i) A clean linen inspection and mending room or area.

(ii) If not provided elsewhere, a clean linen inspection, delinting, folding, assembly, and packaging area should be provided as part of the linen services.

(iii) Mending should be provided for in the linen services department.

(iv) A space for tables, shelving, and storage should be provided; and

(E) Handwashing stations in each area where unbagged soiled linen is handled.

(c)(1) If linen is processed in a laundry facility that is not part of the licensed facility, provisions shall also be made for:

(A) A service entrance, protected from inclement weather, for loading and unloading of linen; and

(B) Control station for pickup and receiving.

(2) The hospital is responsible for ensuring the commercial laundry does comply with 20 CAR § 43-141, physical environment.

(d) If linen is processed in a laundry facility that is part of the licensed facility, the following shall be provided in addition to that of subsection (b) of this section:

(1)(A) A receiving, holding, and sorting room for control and distribution of soiled linen.

(B) Discharge from soiled linen chutes may be received within this room or in a separate room;

(2)(A) Laundry processing room with commercial-type equipment that can process at least a seven-day supply within the regular scheduled workweek.

(B) This may require a capacity for processing a seven-day supply in a forty-hour week;

(3) Storage for laundry supplies;

(4) Employee handwashing stations in each room where clean or soiled linen is processed and handled;

(5) Arrangement of equipment that will:

(A) Permit an orderly workflow; and

(B) Minimize cross-traffic that might mix clean and soiled operations; and

(6) Conveniently accessible staff:

(A) Lockers;

(B) Showers; and

(C) Lounge.

20 CAR § 43-164. Physical facilities — Cleaning and sanitizing carts, employee facilities, and environmental closets.

(a)(1) Facilities shall be provided to clean and sanitize carts serving the central medical and surgical supply department, dietary facilities, and linen services.

(2) These may be centralized, departmentalized, or offsite as required by the written narrative.

(b)(1) Lockers, lounges, toilets, etc., should be provided for employees and volunteers.

(2) These should be in addition to, and separate from, those required for medical staff and public.

(c)(1) Each environmental services closet shall contain:

(A) A floor receptor and/or services sink; and

(B) Storage space for environmental services equipment (cart, bucket, etc.) and supplies.

(2) There shall be at least one (1) environmental services closet for each floor.

20 CAR § 43-165. Physical facilities — Engineering service and equipment areas.

(a)(1) Space shall be included in all mechanical and electrical equipment rooms for proper maintenance of equipment.

(2) Provisions shall also be made to provide for equipment removal and replacement.

(b) The following shall be provided:

(1) Boilers, mechanical equipment, and electrical equipment shall be located in ventilated rooms or buildings except as noted below:

(A) Rooftop air conditioning and ventilation equipment installed in weatherproof housings;

(B) Standby generators where the engine and appropriate accessories (i.e., batteries) are properly heated and enclosed in a weatherproof housing as recommended by the manufacturer;

- (C) Cooling towers and heat-rejection equipment;
 - (D) Electrical transformers and switchgear where:
 - (i) Required to serve the facility; and
 - (ii) Installed in a weatherproof housing;
 - (E) Medical gas parks and equipment;
 - (F) Air-cooled chillers where installed in a weatherproof housing;
 - (G)(i) Waste processing equipment.
 - (ii) Site lighting, post indicator valves, and other equipment normally installed on the exterior of the building;
 - (H) Site lighting, post indicator valves, and other equipment normally installed on the exterior of the building; and
 - (I) Exhaust fans;
- (2)(A) Engineer's office with file space and provisions for secured storage of facility drawings, records, manuals, etc.
- (B) The engineer's office shall be a separate and distinct space dedicated for the purpose;
- (3) General maintenance shop or shops for repair and maintenance as required by the functional program;
- (4)(A) Storage room for building maintenance supplies.
- (B) Storage for solvents and flammable liquids shall comply with applicable NFPA codes;
- (5) Yard equipment and supply storage shall be located so equipment may be moved directly to exterior without interfering with other work; and
- (6)(A) Separate area or room specifically for storage, repair, and testing of electronic and other medical equipment.
- (B) The amount of space and type of utilities will vary with the:
- (i) Type of equipment involved; and
 - (ii) Types of outside contracts used.

20 CAR § 43-166. Physical facilities — Waste processing services.

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(a) Hazardous waste and antineoplastic agent disposal.

(1) The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport, and disposal of hazardous waste.

(2) The policies and procedures shall conform with the latest edition of Hazardous Waste Management, 8 CAR pt. 81, Division of Environmental Quality, Little Rock, Arkansas.

(3) Within the facility, hazardous waste, especially antineoplastic agents, shall be labeled in a manner that it shall be easily recognized from all other waste.

(4) The facility shall compile a list of all antineoplastic agents used in the facility.

(5) The facility shall have policies and procedures for:

(A) The cleanup of spills; and

(B) Decontamination and treatment of personnel exposed to hazardous waste and antineoplastic agents.

(b) Radioactive waste disposal.

(1) The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport, and disposal of radioactive waste and materials.

(2) All policies and procedures shall conform to the most current Rules for Control of Sources of Ionizing Radiation, 20 CAR pt. 3, Department of Health, Little Rock, Arkansas.

(3) The facility shall maintain records of all radioactive waste and materials that have been disposed.

(c) Regulated medical waste (infectious waste) disposal.

(1) The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport, and disposal of regulated medical waste.

(2) All policies and procedures shall conform to the latest edition of the.

(3) The facility shall have policies and procedures for:

(A) The cleanup of spills; and

(B) Decontamination and treatment of personnel exposed to regulated medical waste.

(d) **Solid waste disposal — Noninfectious waste.**

(1) The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport, and disposal of solid waste.

(2) Policies and procedures shall conform with the latest edition of the Solid Waste Management Rules, 8 CAR pt. 60, Department of Energy and Environment, Little Rock, Arkansas.

(e) **Nuclear waste disposal.**

(1) The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport, and disposal of nuclear waste.

(2) All policies and procedures shall conform to 10 C.F.R. pt. 20 and 10 C.F.R. pt. 35, concerning the handling and disposal of nuclear materials in healthcare facilities.

(f)(1) Containers of hazardous and antineoplastic agent waste, radioactive waste, and regulated medical waste shall be closed except when receiving waste.

(2)(A) Containers that have swinging lids or lids that are easily contaminated are prohibited.

(B) Open containers shall be emptied between patients and the container disinfected.

(C) Containers shall be kept closed except when receiving waste.

(g) **Other waste.** The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport, and disposal of any waste not specifically mentioned in this part.

20 CAR § 43-167. Physical facilities — Details and finishes.

(a) All details for alteration or expansion projects as well as for new construction shall comply with the following.

(b) **Details.**

(1)(A) Compartmentation, exits, automatic extinguishing systems, and other details relating to fire prevention and fire protection shall:

(i) Comply with requirements listed in the NFPA-referenced codes;
and

(ii) Be shown on the fire protection plan.

(B) The Fire Safety Evaluation System (FSES) is an acceptable means of determining Life Safety Code compliance.

(2)(A) Minimum corridor width shall be eight feet (8') clear without projections.

(B) Increased width shall be provided at:

(i) Elevator lobbies; and

(ii) Other places where conditions may demand more clearance.

(C) All service or administrative corridors shall not be less than forty-four inches (44") in width.

(D) Doors to patient rooms shall be a minimum door size of three feet eight inches wide and seven feet high (3' 8" x 7') to provide clearance for movement of beds and other equipment.

(E) Alternatively, NFPA 101 shall be deemed to meet requirements.

(3)(A) Items such as drinking fountains, telephone booths, and vending machines, shall be located so as not to project into exit access corridors.

(B) Incidental items shall be determined by the licensing agency.

(4) Rooms containing bathtubs, sitz baths, showers, and water closets, subject to occupancy by patients shall be equipped with doors and hardware that shall permit access from the outside in any emergency.

(5)(A) All doors between corridors, rooms, or spaces subject to occupancy, except elevator doors, shall be of the swing type.

(B) Openings to showers, baths, patient toilets, ICU patient compartments with the breakaway feature, and other such areas not leading to fire exits shall be exempt from this standard.

(6) All patient room doors located on exit access corridors shall have positive latching hardware.

(7)(A) Doors to patients' toilet rooms and other rooms needing access for wheelchairs shall have a minimum width of thirty-six inches (36") for new facilities.

(B) Alcoves and similar spaces that generally do not require doors are excluded from this requirement.

(8)(A) Windows shall be:

(i) Designed so that persons cannot accidentally fall out of them when they are open; or

(ii) Provided with security screens.

(B) Operation of windows shall be restricted to inhibit possible escape or suicide.

(C) Where the operation of windows or vents requires the use of tools or keys, tools or keys shall be:

(i) On the same floor; and

(ii) Easily accessible to staff.

(9)(A) Glass doors, lights, sidelights, borrowed lights, and windows located within twelve inches (12") of a door jamb with a bottom frame height of less than sixty inches (60") above the finished floor shall be constructed of:

(i) Safety glass;

(ii) Wired glass; or

(iii) Plastic, break-resistant material that creates no dangerous cutting edges when broken.

(B) Similar materials shall be used for wall openings in active areas such as recreation rooms and exercise rooms unless otherwise required for fire safety.

(C) Safety glass-tempered or plastic glazing materials shall be used for shower doors and bath enclosures.

(D) Plastic and similar materials used for glazing shall comply with the flame spread ratings of NFPA 101.

(E) Safety glass or plastic glazing materials, as noted above, shall also be used for interior windows and doors including those in pediatric and psychiatric unit corridors.

(F) In renovation projects, only glazing within eighteen inches (18") of the floor shall be changed to:

- (i) Safety glass;
- (ii) Wired glass; or
- (iii) Plastic, break-resistant material.

(G) NFPA 101 contains additional requirements for glazing in exit corridors, etc., especially in buildings without sprinkler systems.

(10)(A) Where labeled fire doors are required, these shall be certified by an independent test laboratory as meeting the construction requirements equal to those for fire in NFPA Standard 80.

(B) Reference to a labeled door shall be construed to include labeled frame and hardware.

(11)(A) Trash chutes shall be in accordance with NFPA Standard 82.

(B) In addition, linen and refuse chutes shall meet or exceed the following requirements:

(i) Service openings to chutes shall not be located in corridors or passageways but shall be located in a room that complies with NFPA 101;

(ii) Service openings to chutes shall have approved self-closing Class B one and one-half (1 1/2) hour labeled fire doors;

(iii) Minimum cross-sectional dimensions of gravity chutes shall not be less than two feet (2');

(iv)(a) Chutes shall discharge directly into collection rooms separate from:

- (1) Incinerator;
- (2) Laundry; or
- (3) Other services.

(b) Separate collection rooms shall be provided for trash and for linen.

(c) Chute discharge into collection rooms shall comply with NFPA 101; and

(v)(a) Gravity chutes shall extend through the roof with provisions for continuous ventilation as well as for fire and smoke ventilation.

(b) Openings for fire and smoke ventilation shall:

(1) Have an effective area of not less than that of the chute cross-section; and

(2) Be not less than:

(A) Four feet (4') above the roof; and

(B) Six feet (6') clear of other vertical surfaces.

(c) Fire and smoke ventilating openings may be covered with single strength sheet glass.

(12) Dumbwaiters, conveyors, and material handling systems shall comply with NFPA 101.

(13)(A) Thresholds and expansion joint covers shall be installed flush with the floor surface to facilitate use of wheelchairs and carts.

(B) Expansion and seismic joints shall be constructed to restrict the passage of smoke.

(14)(A) Grab bars shall be provided in all patients':

(i) Toilets;

(ii) Showers;

(iii) Tubs; and

(iv) Sitz baths.

(B) The bars shall have:

(i) One and one-half inch (1 1/2") clearance to walls; and

(ii) Sufficient strength and anchorage to sustain a concentrated load of two hundred fifty pounds (250 lbs.).

(15) Soap dishes, soap dispensers, and/or other devices shall be provided at:

(A) Showers;

(B) Bathtubs; and

(C) All handwashing stations except scrub sinks.

(16)(A) Location and arrangement of handwashing stations shall permit proper use and operation.

(B) All sinks except public toilets, janitor closets, and sinks used by patients only shall have foot, knee, or wrist blade faucets.

(C) Particular care shall be given to the clearances required for blade-type operating handles.

(17)(A) Mirrors shall not be installed at handwashing fixtures in:

- (i) Food preparation areas;
- (ii) Nurseries;
- (iii) Clean and sterile supply areas;
- (iv) Scrub sinks; or
- (v) Other areas where asepsis is essential.

(B) Provisions for hand drying shall be included at all handwashing stations except scrub sinks.

(C) Paper units shall be enclosed to:

- (i) Protect against dust or soil; and
- (ii) Ensure single unit dispensing.

(18) Lavatories and handwashing stations shall be securely anchored to withstand an applied downward vertical load of not less than two hundred fifty pounds (250 lbs.) on the front of the fixture.

(19) Radiation protection requirements of X-ray and gamma ray installations shall conform with Rules for Control of Sources of Ionizing Radiation, 20 CAR pt. 3, Department of Health.

(20) The minimum ceiling height shall be seven feet ten inches (7' 10") with the following exceptions:

(A) Boiler rooms shall have ceiling clearances not less than two feet six inches (2' 6") above the:

- (i) Main boiler header; and
- (ii) Connecting piping;

(B) Ceilings in radiographic, operating and delivery rooms, and other rooms containing ceiling-mounted equipment or ceiling-mounted surgical light fixtures shall be of sufficient height to accommodate:

(i) The equipment or fixtures; and

(ii) Their normal movement;

(C)(i) Ceilings in corridors, storage rooms, and toilet rooms shall be not less than seven feet eight inches (7' 8") in height.

(ii) Ceiling heights in small, normally unoccupied spaces may be reduced; and

(D) Seclusion treatment rooms shall have a minimum ceiling height of nine feet (9').

(21) Recreation rooms, exercise rooms, and similar spaces where impact noises may be generated shall not be located directly over patient bed area, delivery, or operating suites unless special provisions are made to minimize such noise.

(22) Rooms containing heat-producing equipment, such as boiler or heater rooms and laundries, shall be insulated and ventilated to prevent any floor or partition surface from exceeding a temperature of ten degrees Fahrenheit (10°F) above ambient room temperature.

(23)(A) Noise reduction criteria shown in Table 2 of Appendix A shall apply to partition, floor, and ceiling construction in patient areas.

(B) Careful attention shall be given to penetrations.

(24)(A) Approved fire extinguishers shall be provided in locations throughout the building in accordance with NFPA Standard No. 10.

(B) Extinguishers located in exit corridors shall be recessed.

(25)(A) Offsite buildings or freestanding buildings used for storage of archived patient medical records shall:

(i) Be built of noncombustible materials; and

(ii) Provide security and smoke detection systems for the records.

(B) Records shall be:

(i) Arranged in an accessible manner; and

(ii) Stored at least six inches (6") above the floor.

(C) Records shall be protected against undue destruction from dust, vermin, water, etc.

(D) X-ray film storage is not required to meet the above requirements.

(26)(A) Light fixtures shall be provided with protective covers in:

- (i) Food preparation;
- (ii) Serving areas; and
- (iii) Patient care and treatment spaces.

(B) Protective light fixture covers are not required in corridors.

(27) Minimum distance between patient room windows and adjacent structures shall be thirty feet (30') (new construction only).

(28) A panic bar releasing device shall be provided for all required exit doors subject to patient traffic (new construction only).

(29) Doors in smoke barrier partitions shall comply with NFPA 101.

(30) Fire-rated roof-ceiling assemblies shall be listed with a nationally recognized laboratory.

(31)(A) Mechanical smoke door coordinators shall not be used.

(B) Adjustable hydraulic closures or the full-length header type shall be used.

(32)(A) Corridor partitions, smoke stop partitions, horizontal exit partitions, exit enclosures, and fire-rated walls required to have protected openings shall be effectively and permanently identified with signs or stenciling in a manner acceptable to the Division of Health Facilities Services.

(B) Such identification shall be:

- (i) Above any decorative ceiling; and
- (ii) In concealed spaces.

(c) Finishes.

(1) Cubicle curtains and draperies shall be noncombustible or rendered flame-retardant and shall pass both the:

- (A) Large-scale and small-scale tests of NFPA Standard 701; and
- (B) Requirements of NFPA 13 when applicable.

(2) Flame spread, fuel contributed, smoke density, and critical radiant flux of finishes shall comply with NFPA 101.

(3)(A) Floors in areas and rooms in which anesthetic agents are stored or administered to patients shall comply with NFPA Standard 99.

(B) Conductive flooring may be omitted in anesthetizing areas where:

(i) A written resolution is signed by the hospital board stating that no flammable anesthetic agents shall be used; and

(ii) Appropriate notices are permanently and conspicuously affixed to the wall in each such area and room.

(4)(A) Floor materials shall:

(i) Be easily cleanable; and

(ii) Have wear resistance appropriate for the location involved.

(B) Floors in areas used for food preparation or food assembly shall be water-resistant and greaseproof.

(C) Joints in tile and similar material in such areas shall be resistant to food acids.

(D) In all areas frequently subject to wet cleaning methods, floor-materials shall not be physically affected by germicidal and cleaning solutions.

(E) Floors that are subject to traffic while wet such as shower and bath areas, kitchens, and similar work areas shall have a nonslip surface.

(F) Any facility designed to install carpet shall have prior approval from the department.

(G) The prior approval in part shall be contingent upon:

(i) Submission of a laboratory test report from an approved independent laboratory indicating that the proposed carpet meets or exceeds the requirements listed in NFPA 101; and

(ii) Agreement by the department as to the specific areas in which carpet is to be used.

(H) In all carpet installations, no rubber backings or rubber padding shall be permitted except in cases where the:

(i) Carpet and backing are tested as an integral component; and

(ii) Integral component meets the requirements listed in NFPA 101.

(I) Carpet shall not be allowed in the following areas or rooms:

- (i) Operating rooms;
- (ii) Delivery rooms;
- (iii) Emergency rooms;
- (iv) Intensive care units;
- (v) Nursery;
- (vi) Recovery;
- (vii) Kitchens;
- (viii) Laboratories;
- (ix) LDR and LDRP rooms;
- (x) Clean and soiled holding/workrooms; and
- (xi) Isolation rooms.

(J) Operating rooms shall have a seamless floor.

(5) Wall bases in kitchens, operating rooms, soiled workrooms, and other areas that are frequently subject to wet cleaning methods shall be made integral and:

- (A) Coved with the floor;
- (B) Tightly sealed within the wall; and
- (C) Constructed without voids that can harbor insects.

(6)(A) Wall finishes shall be washable.

(B) In the vicinity of plumbing fixtures, shall be smooth and water resistant.

(7) Floors and walls penetrated by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects.

(8) Ceilings in food preparation and storage areas shall be cleanable with routine housekeeping equipment.

(9) Operating rooms, trauma rooms, delivery rooms for Caesarean sections, and protective isolation rooms shall have ceilings with a smooth-finish plaster or gypsum board surface with a minimum of fissures, equipped with access panels where needed.

(10)(A) In psychiatric patient rooms, toilets, and seclusion rooms, ceiling construction shall be smooth-finish plaster or gypsum board surface with a minimum of fissures.

(B) Ceiling-mounted air and lighting devices shall be security-type.

(C) Ceiling-mounted sprinkler heads shall be of the concealed type.

(11) Ceilings shall be cleanable and in the following areas shall be washable, waterproof, and smooth-finish plaster, gypsum board, or vinyl-faced acoustic panels:

(A) Cardiac cath labs;

(B) Surgical suite corridors;

(C) Delivery suite corridors;

(D) Central sterilization suite;

(E) Autopsy rooms;

(F) Bacteriology;

(G) Mycology;

(H) Media preparation rooms;

(I) Glass-washing rooms located in the labs;

(J) Soiled holding rooms;

(K) Soiled and clean utility rooms;

(L) Emergency suite treatment rooms; and

(M) Trauma rooms.

(12) Finished ceilings may be omitted in mechanical, electrical, and equipment spaces and shops.

(13) Finished ceilings shall be provided for corridors in patient areas.

(14) Sound-sensitive areas such as neonatal intensive care may have special floor and ceiling treatments.

20 CAR § 43-168. Physical facilities — Construction, including fire-resistive requirements.

(a) **Design.** Every building and every portion thereof shall be designed and constructed to sustain all dead and live loads in accordance with the American Society of Civil Engineers (ASCE), "Minimum Design Loads for Buildings and Other Structures".

(b) **Foundations.**

(1) Foundations shall rest on natural solid bearing if a satisfactory bearing is available at reasonable depths.

(2) Proper soil-bearing values shall be established in accordance with recognized standards.

(3) If solid bearing is not encountered at practical depths, the structure shall be supported on drive piles or drilled piers designed to support the intended load without detrimental settlement, except that one-story buildings may rest on a fill designed by a soils engineer.

(4) When engineered fill is used, site preparation and placement of fill shall be performed under the direct full-time supervision of the soils engineer.

(5) The soils engineer shall issue:

(A) A final report on the compacted fill operation; and

(B) Certification of compliance with the job specifications.

(6) All footings shall extend to a depth not less than one foot (1') below the estimated maximum frost line.

(c) **Construction.**

(1)(A) Construction shall comply with the applicable requirements of NFPA 101, the Arkansas Fire Prevention Code Volumes I and II, and Title 22, Subchapter B, Building Authority Minimum Standards and Criteria, Part 111 Design Review Section, Accessibility for Individuals with Disabilities Standards, 22 CAR § 111-1001 et seq.

(B) **Note.**

(i) NFPA 101 generally covers fire/safety requirements only, whereas most model codes also apply to structural elements.

(ii) The fire/safety items of NFPA 101 would take precedence over other codes in case of conflict.

(iii) In the event NFPA 101 does not specifically address a life safety requirement found only in the Arkansas Fire Prevention Code, compliance with the requirement is not mandatory.

(iv) Appropriate application of each would minimize problems.

(v) For example, some model codes require closers on all patient doors.

(vi) NFPA 101 recognizes the potential fire/safety problems of this requirement and stipulates that if closers are used for patient room doors, smoke detectors shall also be provided within each affected patient room.

(2)(A) For renovation projects, the extent of new construction shall be determined by the licensing agency.

(B) Construction shall comply with applicable requirements of NFPA 101.

(d) Freestanding buildings for patient use.

(1) Buildings of this element category are considered to be:

(A) Greater than thirty feet (30') from the hospital; or

(B) Separated from the hospital by two-hour fire-resistance-rated construction.

(2) Buildings housing nonsleeping patient areas shall comply with NFPA 101.

(e) **Freestanding buildings.** Separate freestanding buildings over thirty feet (30') from an inpatient facility housing the boiler plant, laundry, shops, or general storage shall be built in accordance with applicable building codes for such occupancy.

(f) Interior finishes.

(1) Interior finish materials shall comply with the limitations as indicated in NFPA 101.

(2) If a separate underlayment is used with any floor finish materials, the underlayment and the finish material shall be tested as a unit.

(3) Tests shall be performed by an approved independent testing laboratory.

(g) **Insulation materials.** Building insulation materials, unless sealed on all sides and edges, shall have a flame spread rating of twenty-five (25) or less and a smoke-

developed rating of one hundred fifty (150) or less when tested in accordance with NFPA 255.

(h) **Flood protection.**

(1) Executive Order 11296 was issued to minimize financial loss from flood damage to facilities constructed with federal assistance.

(2) In accordance with that order, possible flood effects shall be considered when selecting and developing the site.

(3) Insofar as possible, new facilities shall not be located on designated flood plains.

(4) Where this is unavoidable, consult with the United States Army Corps of Engineers regional office for:

(A) The latest applicable regulations pertaining to flood insurance; and

(B) Protection measures that may be required.

(i) **Elevators.**

(1)(A) All hospitals having patient facilities such as bedrooms, dining rooms, or recreation areas or critical services such as operating, delivery, diagnostic, or therapeutic located on other than the grade-level entrance floor shall have electric or hydraulic elevators.

(B)(i) Installation and testing of elevators shall comply with:

(a) American National Standards Institute and American Society of Mechanical Engineers ANSI/ASME Standard A17.1, Safety Code for Elevators and Escalators for new construction; and

(b) American National Standards Institute and American Society of Mechanical Engineers ANSI/ASME Standard A17.3, Safety Code for Existing Elevators and Escalators for existing facilities.

(ii) See American Society of Civil Engineers ASCE Standard 7-93: Minimum Design Loads for Buildings and Other Structures for seismic design and control systems requirements for elevators.

(2) In the absence of an engineered traffic study, the following guidelines for number of elevators shall apply:

(A) At least one (1) hospital-type elevator shall be installed when one (1) to fifty-nine (59) patient beds are located on any floor other than the main entrance floor;

(B)(i) At least two (2) hospital-type elevators shall be installed:

(a) When sixty (60) to two hundred (200) patient beds are located on floors other than the main entrance floor; or

(b) Where the major inpatient services are located on a floor other than those containing patient beds.

(ii) Elevator service may be reduced for those floors providing only partial inpatient services;

(C)(i) At least three (3) hospital-type elevators shall be installed:

(a) Where two hundred one (201) to three hundred fifty (350) patient beds are located on floors other than the main entrance floor; or

(b) Where the major inpatient services are located on a floor other than those containing patient beds.

(ii) Elevator service may be reduced for those floors that provide only partial inpatient services; and

(D) For hospitals with more than three hundred fifty (350) beds, the number of elevators shall be determined from:

(i) A study of the hospital plan; and

(ii) The expected vertical transportation requirements.

(3)(A) Hospital-type elevator cars shall have inside dimensions that accommodate a patient bed with attendants.

(B) Cars shall be at least five feet eight inches wide by nine feet deep (5' 8" x 9').

(C) Car doors shall have a clear opening of not less than four feet wide and seven feet high (4' x 7').

(D) In renovations, existing elevators that can accommodate patient beds used in the facility will not be required to be increased in size.

(E) **Note.** Additional elevators installed for visitors and material handling may be smaller than noted above, within restrictions set by standards for disabled access.

(4) Elevators shall be equipped with a two-way automatic level-maintaining device with an accuracy of one-fourth inch (1/4").

(5) Each elevator, except those for material handling, shall be equipped with an independent keyed switch for staff use for:

(A) Bypassing all landing button calls; and

(B) Responding to car button calls only.

(6)(A) Elevator call buttons and controls shall not be activated by heat or smoke.

(B) Light beams, if used for operating door reopening devices without touch, shall be:

(i) Used in combination with door-edge safety devices; and

(ii) Interconnected with a system of smoke detectors.

(C) This is so the light control feature will be overridden or disengaged should it encounter smoke at any landing.

(7) Field inspections and tests shall be made and the owner shall be furnished with written certification stating the installation meets the requirements set forth in this section as well as all applicable safety regulations and codes.

20 CAR § 43-169. Physical facilities — Mechanical requirements.

(a) General.

(1)(A) Prior to acceptance of the facility, all mechanical systems shall be tested and operated to demonstrate to the owner or his or her designated representative that the installation and performance of these systems conform to design intent.

(B) Test results shall be documented for maintenance files.

(2)(A) Upon completion of the special systems equipment installation contract, the owner shall be furnished with:

(i) A complete set of manufacturers' operating, maintenance, and preventive instructions;

(ii) A parts list; and

(iii) Complete procurement numbers and descriptions.

(B) Operating staff shall be provided with instructions for proper operation of systems and equipment.

(3) Rotating mechanical equipment, shall be mounted on vibration isolators as required to prevent unacceptable structure-borne vibration.

(4) Supply and return mains and risers for cooling, heating, and steam systems shall be equipped with valves to isolate the various sections of each system and each piece of equipment.

(b) Thermal and acoustical insulation.

(1) Insulation within the building shall be provided to:

(A) Conserve energy;

(B) Protect personnel;

(C) Prevent vapor condensation; and

(D) Reduce noise.

(2)(A) Insulation on cold surfaces shall include an exterior vapor barrier.

(B) Material that will not absorb or transmit moisture will not require a separate vapor barrier.

(3) Insulation, including finishes and adhesives on the exterior surfaces of ducts, piping, and equipment, shall have a flame spread rating of twenty-five (25) or less and a smoke-developed rating of fifty (50) or less as determined by an independent testing laboratory in accordance with NFPA 255.

(4)(A) Interior duct linings shall not be used.

(B) This requirement shall not apply to air terminals and sound attenuation devices that have special coverings over such linings.

(5) Existing accessible insulation within areas that are renovated shall be inspected and addressed as appropriate.

(c) **Steam and hot water systems and pressure vessels.** All pressure vessels shall meet the requirements of the Chief Inspector of the Boiler Inspection Division of the Division of Labor.

(d) **Air conditioning, heating, and ventilating systems.** The following provision:

(1)(A) The systems shall be designed to provide the dry bulb temperatures noted in Table 3 of Appendix A.

(B) The systems shall be designed and operated to provide the relative humidity noted in Table 3 of Appendix A.

(2)(A) All rooms and areas in the facility used for patient care shall have provisions for ventilation.

(B) The ventilation rates shown in Table 4 of Appendix A shall be used only as minimum standards; they do not preclude the use of higher, more appropriate rates.

(C) Fans serving exhaust systems shall be:

- (i) Located at the discharge end; and
- (ii) Readily serviceable.

(D) Air supply and exhaust in rooms for which no minimum total air change rate is noted may vary down to zero (0) in response to room load.

(E) For rooms listed in Table 4 of Appendix A where VAV systems are used, minimum total air change shall be within limits noted.

(F) Temperature control shall also comply with these standards.

(G) To maintain asepsis control, airflow supply and exhaust should generally be controlled to ensure movement of air from "clean" to "less-clean" areas, especially in critical areas.

(H) The ventilation systems shall be designed and balanced according to the requirements shown in:

- (i) Table 4 of Appendix A; and
- (ii) The applicable notes.

(3)(A) Exhaust systems may be combined to enhance the efficiency of recovery devices required for energy conservation.

(B) Local exhaust systems shall be used whenever possible in place of dilution ventilation to reduce exposure to hazardous:

- (i) Gases;
- (ii) Vapors;
- (iii) Fumes; or
- (iv) Mists.

(C) Airborne infection isolation rooms shall not be served by exhaust systems incorporating energy recovery devices that permit cross-contamination.

(4)(A) Fresh-air intakes shall be located at least twenty-five feet (25') from exhaust outlets of:

- (i) Ventilating systems;
- (ii) Combustion equipment stacks;
- (iii) Medical-surgical vacuum systems;
- (iv) Plumbing vents; or
- (v) Areas that may collect vehicular exhaust or other noxious fumes.

(B) Prevailing winds and/or proximity to other structures may require greater clearances.

(C) Plumbing and vacuum vents that terminate at a level above the top of the air intake may be located as close as ten feet (10').

(D) The bottom of outdoor air intakes serving central systems shall be as high as practical but:

- (i) At least six feet (6') above ground level; or
- (ii) If installed above the roof, three feet (3') above roof level.

(E) Exhaust outlets from areas that may be contaminated shall be:

- (i) Above roof level; and
- (ii) Arranged to minimize recirculation of exhaust air into the building.

(5)(A) In new construction and major renovation work, air supply for operating and delivery rooms, excluding LDR/LDRP rooms, shall be from ceiling outlets near the center of the work area.

(B) Return air shall be near the floor level.

(C) Each operating and delivery room shall have at least two (2) return-air inlets located as remotely from each other as practical.

(D) Design should consider turbulence and other factors of air movement to minimize fall of particulates onto sterile surfaces.

(E) Where extraordinary procedures such as organ transplants justify special designs, installation shall properly meet performance needs as determined by applicable standards.

(F) These special designs should be reviewed on a case-by-case basis.

(G) Temperature shall be individually controlled for each operating and Caesarean section room.

(6)(A) The operating and delivery room, excluding LDR/LDRP rooms, room ventilation systems should operate at all times to maintain the "air movement relationship to adjacent areas".

(B) The cleanliness of the spaces is compromised when the ventilation system is shut down, e.g., airflow from a less-clean space such as the corridor can occur, and standing water can accumulate in the ventilation system near humidifiers or cooling coils.

(7)(A) In new construction and major renovation work, air supply for rooms used for invasive procedures such as autopsy rooms, cardiac cath labs, cystoscopic rooms, trauma rooms, endoscopy rooms, bronchoscopy rooms, and/or rooms where anesthesia gases are used shall be from ceiling outlets near the center of the room and/or work area.

(B) Return or exhaust air inlets shall be near the floor level.

(C) Exhaust inlets for anesthesia evacuation and other special applications shall be permitted to be installed in the ceiling.

(8)(A) Each space routinely used for administering inhalation anesthesia and inhalation analgesia shall be served by a scavenging system to vent waste gases.

(B) If a vacuum system is used, the gas-collecting system shall be arranged so that it does not disturb patients' respiratory systems.

(C) Gases from the scavenging system shall be exhausted directly to the outside.

(D) The anesthesia evacuation system may be combined with the room exhaust system, provided the part used for anesthesia gas scavenging:

(i) Exhausts directly to the outside; and

(ii) Is not part of the recirculation system.

(E) Scavenging systems are not required for areas where gases are used only occasionally such as the emergency room, offices for routine dental work, etc.

(9) The bottoms of ventilation openings shall be at least three inches (3") above the floor.

(10)(A) The space above ceilings in new construction shall not be used as plenum space to supply to, return air from, or to exhaust air from any:

(i) Patient room;

(ii) Operating room;

(iii) Trauma room;

(iv) Critical care room;

(v) Delivery room;

(vi) Endoscopy room;

(vii) Cardiac cath lab;

(viii) Bronchoscopy room;

(ix) Autopsy room;

(x) Exam room;

(xi) Treatment room;

(xii) Airborne infection isolation room;

(xiii) Protective environment room;

(xiv) Radiology suite

- (xv) Laboratory suite;
- (xvi) Soiled workroom;
- (xvii) Soiled holding;
- (xviii) Physical therapy and hydrotherapy;
- (xix) ETO-sterilizer room;
- (xx) Sterilizer equipment room; and
- (xxi) Central medical and surgical supply areas or rooms.

(B) Plenum return air space conforming to NFPA 90A requirements shall be acceptable in areas where it is not listed above.

(11)(A) All central ventilation or air conditioning systems shall be equipped with filters with efficiencies equal to or greater than those specified in Table 1 of Appendix A.

(B) Where two (2) filter beds are required:

(i) Filter bed number one (1) shall be located upstream of the air conditioning equipment; and

(ii) Filter bed number two (2) shall be downstream of any fan or blowers.

(C) Filter efficiencies tested in accordance with ASHRAE 52-92, shall be average.

(D) Filter frames shall be durable and proportioned to provide an airtight fit with the enclosing ductwork.

(E) All joints between filter segments and enclosing ductwork shall have gaskets or seals to provide a positive seal against air leakage.

(F) A manometer or equal equivalent method of monitoring high and low pressure drop shall be installed across each filter bed having a required efficiency of ninety percent (90%) or more, including hoods requiring HEPA filters.

(12)(A) If duct humidifiers are located upstream of the final filters, they shall be located in a manner to prevent condensation on the surface of the filters.

(B) Ductwork with duct-mounted humidifiers shall have a means of water removal.

(C) An adjustable high-limit humidistat shall be located downstream of the humidifier to reduce the potential of condensation inside the duct.

(D) All duct take-offs should be sufficiently downstream of the humidifier to ensure complete moisture absorption.

(E) Steam humidifiers shall be used.

(F) Reservoir-type water spray or evaporative pan humidifiers shall not be used.

(13) Air-handling duct systems shall:

(A) Be designed with accessibility for duct cleaning; and

(B) Meet the requirements of NFPA 90A.

(14) Ducts that penetrate construction intended to protect against X-ray, magnetic, RFI, or other radiation shall not impair the effectiveness of the protection.

(15)(A) Fire and smoke dampers shall be constructed, located, and installed in accordance with the requirements of:

(i) NFPA 101, 90A; and

(ii) The specific damper's listing requirements.

(B) Fans, dampers, and detectors shall be interconnected so that damper activation will not damage ducts.

(C) Maintenance access shall be provided at all dampers.

(D) All damper locations shall be indicated on design drawings.

(E) Dampers should be activated by fire or smoke sensors, not by fan cutoff alone.

(F) Switching systems for restarting fans may be installed for fire department use in venting smoke after a fire has been controlled.

(G) However, provisions should be made to avoid possible damage to the system due to closed dampers.

(H) When smoke partitions are required, heating, ventilation, and air conditioning zones shall be coordinated with compartmentation insofar as practical to minimize need to penetrate fire and smoke partitions.

(16)(A) Hoods and safety cabinets may be used for normal exhaust of a space provided that minimum air change rates are maintained.

(B) If air change standards in Table 4 of Appendix A do not provide sufficient air for proper operation of exhaust hoods and safety cabinets when in use, supplementary makeup air, filtered and preheated, shall be provided around these units to maintain the required airflow direction and exhaust velocity.

(C) Use of makeup air will avoid dependence upon infiltration from outdoor and/or from contaminated areas.

(D) Makeup systems for hoods shall be arranged to:

(i) Minimize "short circuiting" of air; and

(ii) Avoid reduction in air velocity at the point of contaminant capture.

(17) Laboratory hoods shall meet the following general standards:

(A) Have an average face velocity of at least seventy-five (75) feet per minute;

(B) Have an exhaust fan located at the discharge end of the system; and

(C) Have an exhaust duct system of noncombustible corrosion-resistant material as needed to meet the planned usage of the hood.

(18) Laboratory exhaust and ventilation systems shall comply with NFPA 45.

(19) Laboratory hoods shall meet the following special standards:

(A)(i) Fume hoods and their associated equipment in the air stream intended for use with perchloric acid and other strong oxidants, shall be:

(a) Constructed of stainless steel or other material consistent with special exposures; and

(b) Provided with a water wash and drain system to permit periodic flushing of duct and hood.

(ii) Electrical equipment intended for installation within such ducts shall be designed and constructed to resist penetration by water.

(iii) Lubricants and seals shall not contain organic materials.

(iv) When perchloric acid or other strong oxidants are only transferred from one (1) container to another, standard laboratory fume hoods and the associated equipment may be used in lieu of stainless steel construction; and

(B)(i) In new construction and major renovation work, each hood used to process infectious or radioactive materials shall have a minimum face velocity of ninety (90) feet per minute with suitable pressure-independent air-modulating devices and alarms to alert staff of:

(a) Fan shutdown; or

(b) Loss of airflow.

(ii) Each shall also:

(a) Have filters with ninety-nine and ninety-seven hundredths percent (99.97%) efficiency, based on dioctyl-phthalate (DOP) test method, in the exhaust stream; and

(b) Be designed and equipped to permit the safe removal, disposal, and replacement of contaminated filters.

(iii) Filters shall be as close to the hood as practical to minimize duct contamination.

(iv) Fume hoods intended for use with radioactive isotopes shall:

(a) Be constructed of:

(1) Stainless steel; or

(2) Other material suitable for the particular exposure; and

(b) Comply with NFPA 801 for Facilities for Handling Radioactive Materials.

(v) Radioactive isotopes used for injections, etc., without probability of airborne particulates or gases may be processed in a clean-workbench-type hood where acceptable to the Nuclear Regulatory Commission.

(20)(A) Exhaust hoods handling grease-laden vapors in food preparation centers shall comply with NFPA 96.

(B) All hoods over cooking ranges shall be equipped with:

(i) Grease filters;

- (ii) Fire extinguishing systems; and
- (iii) Heat-actuated fan controls.

(C) Cleanout openings shall be provided every twenty feet (20') and at changes in direction in the horizontal exhaust duct systems serving these hoods.

(D) Horizontal runs of ducts serving range hoods should be kept to a minimum.

(21) The ventilation system for anesthesia storage rooms shall conform to the requirements of NFPA 99.

(22) The ventilation system for the space that houses ethylene oxide (ETO) sterilizers should be designed to:

(A)(i) Provide a dedicated (not connected to a return air or other exhaust system) exhaust system.

(ii) Refer to 29 C.F.R. § 1910.1047;

(B)(i) All source areas shall be exhausted, including:

- (a) The sterilizer equipment room;
- (b) Service/aeration areas;
- (c) Over the sterilizer door; and
- (d) The aerator.

(ii) If the ETO cylinders are not located in a well-ventilated, unoccupied equipment space, an exhaust hood shall be provided over the cylinders.

(iii) The relief valve shall be terminated:

- (a) In a well-ventilated, unoccupied equipment space; or
- (b) Outside the building.

(iv) If the floor drain that the sterilizer or sterilizers discharge to is not located in a well-ventilated, unoccupied equipment space, an exhaust drain cap shall be provided (coordinate with local codes);

(C) Ensure that general airflow is away from sterilizer operator or operators; and

(D)(i) Provide a dedicated exhaust duct system for ETO.

(ii) The exhaust outlet to the atmosphere should be at least twenty-five feet (25') away from any air intake.

(23) An audible and visual alarm shall activate in the sterilizer work area and a twenty-four-hour staffed location upon loss of airflow in the exhaust system.

(24) Rooms with fuel-fired equipment shall be provided with sufficient outdoor air to maintain equipment combustion rates.

(25) Gravity exhaust may be used, where conditions permit, for nonpatient areas such as boiler rooms, central storage, etc.

(26)(A) The energy-saving potential of variable air volume systems is recognized, and these standards herein are intended to maximize appropriate use of that system.

(B) Any system utilized for occupied areas shall include provisions to avoid air stagnation in interior spaces where thermostat demands are met by temperatures of surrounding areas.

(27)(A) Special consideration shall be given to the type of heating and cooling units, ventilation outlets, and appurtenances installed in patient-occupied areas of psychiatric units.

(B) The following shall apply:

(i)(a) All air grilles and diffusers shall be of a type that prohibits the insertion of foreign objects.

(b) All exposed fasteners shall be tamper-resistant;

(ii) All convector or HVAC enclosures exposed in the room shall:

(a) Be constructed with round corners; and

(b) Have enclosures fastened with tamper-resistant screws; and

(iii) HVAC equipment shall be of a type that minimizes the need for maintenance with the room.

(28)(A) Rooms or booths used for sputum induction, aerosolized pentamidine treatments, and other high-risk cough-inducing procedures shall be provided with local exhaust ventilation.

(B) See Table 4 of Appendix A for ventilation requirements.

(29)(A) Noncentral air handling systems, i.e., individual room units that are used for heating and cooling purposes (fan-coil units, heat pump units, etc.) in areas permitted by Table 4 of Appendix A to utilize air recirculated by means of a room unit shall be equipped with permanent cleanable or replaceable filters.

(B) The filters shall have a minimum efficiency of sixty-eight percent (68%) weight arrestance.

(C) These units may be used as recirculating units only.

(D) All outdoor air requirements shall be met by a separate central air handling system with the proper filtration as noted in Table 1 of Appendix A.

(30) For special needs pharmacy work area and equipment requirements, refer to the Arkansas State Board of Pharmacy Rules, 17 CAR pt. 160.

20 CAR § 43-170. Physical facilities — Plumbing and other piping systems.

(a) All plumbing systems shall be designed and installed in accordance with the requirements of the latest edition of the:

(1) Arkansas Plumbing Code, 17 CAR pt. 65; and

(2) Administrative Rules of the Boiler Inspection Division, 20 CAR pt. 880, Department of Labor and Licensing.

(b) Plumbing fixtures.

(1) The material used for plumbing fixtures shall be nonabsorbent acid-resistant material.

(2) The water supply spout for lavatories and sinks required in patient care areas, except patient rooms, shall be mounted so that the discharge point is a minimum distance of five inches (5") above the rim of the fixture.

(3)(A) All fixtures used by medical and nursing staff and all lavatories used by patients and food handlers shall be trimmed with valves that can be operated without the use of hands.

(B) Where blade handles are used for this purpose, they shall not exceed four and one-half inches (4 1/2") in length, except that handles on clinical sinks shall be not less than six inches (6") long.

(C) Automatic controls are acceptable.

(D) Scrub sinks shall be trimmed with foot, knee, or ultrasonic controls.

(4) Clinical sinks shall have an integral trap in which the upper portion of the water trap provides a visible seal.

(5) Shower bases and tubs shall provide nonslip walking surfaces.

(c) Potable water supply systems.

(1) Systems shall be designed to supply water at sufficient pressure to operate all fixtures and equipment during maximum demand periods.

(2)(A) Each water service main, branch main, riser, and branch to a group of fixtures shall be valved.

(B) Stop valves shall be provided at each fixture.

(C) Appropriate panels for access shall be provided at all valves where required.

(3) Backflow preventers (vacuum breakers) shall be installed on:

(A) Hose bibs;

(B) Laboratory sinks;

(C) Janitors' sinks;

(D) Bedpan flushing attachments;

(E) Autopsy tables; and

(F) All other fixtures to which hoses or tubing can be attached.

(4)(A) Bedpan flushing devices shall be provided in each inpatient toilet room.

(B) Installation is optional in psychiatric and alcohol-abuse units where patients are ambulatory.

(5) The following standards shall apply to hot water systems:

(A)(i) The water-heating system shall have sufficient supply capacity at the temperatures and amounts indicated in Table 9 of Appendix A.

(ii) Water temperature is measured at the point of use or inlet to the equipment; and

(B)(i) Hot-water distribution systems serving patient care areas shall be under constant recirculation to provide continuous hot water at each hot water outlet.

(ii) The temperature of hot water for showers and bathing shall be appropriate for safe and comfortable use.

(iii) See Table 9 of Appendix A.

(6)(A) Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times.

(B) See Table 9 of Appendix A.

(d) **Drainage systems.** The following standards shall apply to drainage systems:

(1) Drain lines used for acid waste disposal shall be made of acid-resistant material;

(2) Drain lines serving some types of automatic blood-cell counters shall be of carefully selected material that will eliminate potential for undesirable chemical reactions;

(3)(A) Drainage piping should not be installed within the ceiling or exposed in:

(i) Operating and delivery rooms;

(ii) Nurseries;

(iii) Food preparation centers;

(iv) Food serving facilities;

(v) Food storage areas;

(vi) Central services;

(vii) Electronic data processing areas;

(viii) Electric closets; and

(ix) Other sensitive areas.

(B) Where exposed overhead drain piping in these areas is unavoidable, special provisions shall be made to protect the space below from:

(i) Leakage;

(ii) Condensation; or

- (iii) Dust particles;
- (4) Floor drains shall not be installed in operating and delivery rooms;
- (5)(A) If a floor drain is installed in cystoscopy, it shall contain a nonsplash, horizontal-flow flushing bowl beneath the drain plate.
 - (B) **Note.**
 - (i) Floor drains in cystoscopy operating rooms have been shown to disseminate heavily contaminated spray during flushing.
 - (ii) Unless regularly with large amounts of fluid, the trap tends to dry out and permit passage of gases, vapors, odors, insects, and vermin directly into the operating room.
 - (iii) For new construction, if a floor drain is insisted upon by the users, the drain plate should be located away from the operative, preferably with a closed system of drainage.
 - (iv) Alternative methods include:
 - (a) An aspirator/trap installed in a wall connected to the collecting trough of the operating table by a closed, disposable tube system; or
 - (b) A closed system using portable collecting vessels.
 - (v) See NFPA 99;
- (6) Drain systems for autopsy tables shall be designed:
 - (A) To positively avoid splatter or overflow onto floors or back siphonage;and
 - (B) For easy cleaning and trap flushing;
- (7)(A) Building sewers shall discharge into community sewage.
 - (B) Where such a system is not available, the facility shall treat sewage in accordance with local and state regulations;
- (8)(A) Kitchen grease traps shall be located and arranged to permit easy access without the need to enter food preparation or storage areas.
 - (B) Grease traps shall be:
 - (i) Of capacity required; and

(ii) Accessible from outside of the building without need to interrupt any services;

(9) Where plaster traps are used, provisions shall be made for appropriate access and cleaning; and

(10)(A) In dietary areas, floor drains and/or floor sinks shall be of a type that can be easily cleaned by removal of cover.

(B) Provide floor drains or floor sinks:

(i) At all "wet equipment" (i.e., ice machines); and

(ii) As required for wet cleaning of floors.

(C) Provide removable stainless steel mesh in addition to grilled drain cover to prevent entry of large particles of waste that might cause stoppages.

(D) Location of floor drains and floor sinks shall be coordinated to avoid conditions where locations of equipment make removal of covers for cleaning difficult.

(e)(1) The installation, testing, and certification of nonflammable medical gas and air systems shall comply with the requirements of NFPA 99.

(2) See Table 11 of Appendix A for rooms that require station outlets.

(f)(1) Clinical vacuum system installations shall be in accordance with NFPA 99.

(2) See Table 11 of Appendix A for rooms that require station outlets.

(g)(1) All piping except control-line tubing shall be identified.

(2) All valves shall be tagged and a valve schedule shall be provided to the facility owner for permanent record and reference.

(h) When the functional program includes hemodialysis, continuously circulated filtered cold water shall be provided.

(i)(1) Provide condensate drains for cooling coils of a type that may be cleaned as needed without disassembly.

(2) Provide air gap where condensate drains empty into floor drains.

(3) Provide heater elements for condensate lines in freezer or other areas where freezing may be a problem.

(j) No plumbing lines may be exposed overhead or on walls where:

(1) Possible accumulation of dust or soil may create a cleaning problem; or

(2) Leaks would create a potential for food contamination.

20 CAR § 43-171. Physical environment — Electrical standards.

(a) General.

(1)(A) All electrical material and equipment including conductors, controls, and signaling devices shall be:

(i) Installed in compliance with and maintained per applicable sections of NFPA 70 and NFPA 99; and

(ii) Listed as complying with:

(a) Available standards of listing agencies; or

(b) Other similar established standards where such standards are required.

(B) Maintenance and testing of receptacles in patient care areas shall be performed at initial installation, replacement, or servicing of devices.

(C) Records shall be maintained of all tests and rooms or areas tested, with itemized pass/fail indicators.

(2)(A) The electrical installations including alarm, nurse call, and communication systems shall be tested to demonstrate that equipment installation and operation is appropriate and functional.

(B) A written record of performance tests on special electrical systems and equipment shall demonstrate compliance with applicable codes and standards.

(3) Shielded isolation transformers, voltage regulators, filters, surge suppressors, and other safeguards shall be provided as required where power line disturbances are likely to affect:

(A) Data processing; and/or

(B) Automated laboratory or diagnostic equipment.

(b)(1) Main switchboards shall be:

(A) Located in an area separate from plumbing and mechanical equipment; and

(B) Accessible to authorized persons only.

(2) Switchboards shall be:

- (A) Convenient for use;
- (B) Readily accessible for maintenance;
- (C) Away from traffic lanes; and
- (D) Located in dry, ventilated spaces free of:
 - (i) Corrosive or explosive fumes and gases; or
 - (ii) Any flammable material.

(3) Overload protective devices shall operate properly in ambient room temperatures.

(c) Lighting.

(1)(A) The Illuminating Engineering Society (IES) has developed recommended lighting levels for healthcare facilities.

(B) The reader should refer to the IES Handbook.

(2) Approaches to buildings and parking lots and all occupied spaces within buildings shall have fixtures that can be illuminated as necessary.

(3)(A) Patient rooms shall have general lighting and night lighting.

(B) A reading light shall be provided for each patient.

(C) Reading light controls shall be readily accessible to the patient or patients.

(D) Incandescent and halogen light sources that produce heat shall be avoided to prevent burns to the patient and/or bed linen.

(E) The light source should be covered by a diffuser or lens.

(F) Flexible light arms, if used, shall be mechanically controlled to prevent the lamp from contacting the bed linen.

(G) At least one (1) night light fixture in each patient room shall be controlled at the room entrance.

(H) Lighting for coronary and intensive care bed areas shall permit staff observation of the patient while minimizing glare.

(4)(A) Operating and delivery rooms shall have general lighting in addition to special lighting units provided at surgical and obstetrical tables.

(B) General lighting and special lighting shall be on separate circuits.

(5) Nursing unit corridors shall have general illumination with provisions for reducing light levels at night.

(6)(A) Light intensity for staff and patient needs should generally comply with healthcare guidelines set forth in the IES publication.

(B) Consideration should be given to controlling intensity and/or wavelength to prevent harm to the patient's eyes (i.e., retina damage to premature infants and cataracts due to ultraviolet light).

(C) Many procedures are available to satisfy lighting requirements, but the design should consider light quality as well as quantity for effectiveness and efficiency.

(7) An examination light shall be provided for examination, treatment, and trauma rooms.

(8)(A) Light intensity of required emergency lighting shall follow IES guidelines.

(B) Egress and exit lighting shall comply with NFPA 101.

(d) **Receptacles.**

(1)(A) Each operating and delivery room shall have at least six (6) receptacles convenient to the head of the procedure table.

(B) Each operating room shall have at least sixteen (16) simplex or eight (8) duplex receptacles.

(C) Where mobile X-ray, laser, or other equipment requiring special electrical configurations is used, additional receptacles distinctively marked for X-ray or laser use shall be provided.

(2)(A) Each patient room shall have duplex-grounded receptacles.

(B) There shall be one (1):

(i) At each side of the head of each bed;

(ii) For television, if used; and

(iii) On every other wall.

(C) Receptacles may be omitted from exterior walls where construction or room configuration makes installation impractical.

(D) Nurseries shall have at least two (2) duplex-grounded receptacles for each bassinet.

(E) Outlets for general care areas and critical care areas shall be provided for as defined by NFPA 99 and NFPA 70.

(3)(A) Duplex-grounded receptacles for general use shall be installed:

- (i) Approximately fifty feet (50') apart in all corridors; and
- (ii) Within twenty-five feet (25') of corridor ends.

(B) Receptacles in pediatric and psychiatric unit corridors shall be of the tamper-resistant type.

(C) Special receptacles marked for X-ray use shall be installed in corridors of patient areas so that mobile equipment may be used anywhere within a patient room using a cord length of fifty feet (50') or less.

(D) If the same mobile X-ray unit is used in operating rooms and in nursing areas, receptacles for X-ray use shall permit the use of one (1) plug in all locations.

(E) Where capacitive discharge or battery-powered X-ray units are used, special X-ray receptacles are not required.

(4)(A) Electrical receptacle cover plates or electrical receptacles supplied from the emergency systems shall be:

- (i) Distinctively colored; or
- (ii) Marked for identification.

(B) If color is used for identification purposes, the same color shall be used throughout the facility.

(5)(A) For renal dialysis units, two (2) duplex receptacles shall be on each side of a patient bed or lounge chair.

(B) One (1) duplex receptacle on each side of the bed shall be connected to emergency power.

(e) Equipment.

(1) At inhalation anesthetizing locations, all electrical equipment and devices, receptacles, and wiring shall comply with applicable sections of NFPA 99 and NFPA 70.

(2) Fixed and mobile X-ray equipment installations shall conform to Article 517 and Article 660 of NFPA 70.

(3)(A) The X-ray film illuminator unit or units for displaying at least two (2) films simultaneously shall be installed in each operating room, specified emergency treatment rooms, and X-ray viewing room of the radiology department.

(B) All illuminator units within one (1) space or room shall have lighting of uniform intensity and color value.

(4)(A) Ground-fault circuit interrupters (GFCI) shall comply with NFPA 70.

(B) When ground-fault circuit interrupters are used in critical areas, provisions shall be made to ensure the other essential equipment is not affected by activation of one (1) interrupter.

(5) In areas such as critical care units and special nurseries where a patient may be treated with an internal probe or catheter connected to the heart, the ground system shall comply with applicable sections of NFPA 99 and NFPA 70.

(f) Nurse/patient communication station.

(1)(A) In patient areas, each patient room shall be served by at least one (1) nurse/patient communication station for two-way voice communication.

(B) All primary nurse call systems shall be of the electrical/electronic nature.

(C) The signal shall activate an annunciator panel at:

- (i) The nurses' station;
- (ii) A visible signal in the corridor at the patient's door; and
- (iii) Other areas defined by the functional program.

(D) Each bed shall be provided with a call device.

(E) Two (2) call devices serving adjacent beds may be served on one (1) calling station.

(F) Calls shall activate a visible signal:

- (i) In the corridor at the patient's door;
- (ii) In the clean workroom;
- (iii) In the soiled workroom;

- (iv) In medication;
- (v) In charting;
- (vi) In nourishment;
- (vii) In examination/treatment room or rooms; and
- (viii) At the nurses' station.

(G) In multicorridor nursing units, additional visible signals shall be installed at corridor intersections.

(H) In rooms containing two (2) or more nurse/patient communication stations, indicating lights shall be provided at each station.

(I) Nurse/patient communication stations at each calling station shall be equipped with an indicating light that remains lighted as long as the voice circuit is operating.

(2)(A) An emergency call system shall be provided at each inpatient/outpatient:

- (i) Toilet;
- (ii) Bath; and
- (iii) Shower room.

(B) An emergency call shall be accessible to a collapsed patient on the floor.

(C) Inclusion of a pull cord within four to six inches (4" – 6") from the floor will satisfy this standard.

(D) The emergency call shall be designed so that a signal activated at a patient's calling station will initiate a visible and audible signal distinct from the regular nurse/patient communication station that can be turned off only at the patient calling station.

(E) The signal shall activate:

- (i) An annunciator panel at the nurses' station; and
- (ii) A visible signal in the corridor at:
 - (a) The patient's door; and
 - (b) Other areas defined by the narrative program.

(F) Provisions for emergency calls will also be provided in outpatient and treatment areas where patients are subject to incapacitation.

(3) In areas such as critical care, recovery, and pre-op where patients are under constant visual surveillance, the nurse/patient communication call may be limited to a bedside button or station that activates a signal readily seen at the control station.

(4)(A) A staff emergency assistance system for staff to summon additional assistance shall be provided in:

(i) Each operating, delivery, recovery, emergency examination, and/or treatment area;

(ii) Critical care units;

(iii) Nurseries;

(iv) Special procedure rooms;

(v) Cardiac catheterization rooms;

(vi) Stress-test areas;

(vii) Triage;

(viii) Outpatient surgery admission and discharge areas; and

(ix) Areas for psychiatric patients including:

(a) Seclusion and security rooms;

(b) Anterooms and toilet rooms serving them;

(c) Communal toilet and bathing facility rooms; and

(d) Dining, activity, therapy, exam, and treatment rooms.

(B) This system shall annunciate audibly or visually:

(i) In the clean workroom, soiled workroom, medication, charting, nourishment, and examination/treatment room or rooms if provided; and

(ii) At the administrative center of the nursing unit with backup to another staffed area from which assistance can be summoned.

(5)(A) A nurse/patient communication station is not required in psychiatric nursing units, but if it is included, provisions shall be made for:

(i) Easy removal; or

(ii) Covering call button outlets.

(B) In psychiatric nursing units, all hardware shall have tamper-resistant fasteners.

(g) Emergency power shall be provided in accordance with NFPA 99, NFPA 101, and NFPA 110.

(h) Emergency electrical generators shall have a minimum forty-eight (48) hours of onsite fuel.

(i) All healthcare occupancies shall be provided with a fire alarm system in accordance with NFPA 101 and NFPA 72.

(j) Telecommunications and information systems.

(1) Locations for terminating telecommunications and information system devices shall be provided.

(2)(A) A room shall be provided for telecommunications and information systems.

(B) Special air conditioning and voltage regulations shall be provided when recommended by the manufacturer.

(k) Annunciator alarm panels for emergency systems including but not limited to such as the fire alarms, medical gas, and emergency generators shall be located:

(1) According to the functional program; and

(2) In prominent locations easily observed and accessible by staff at all times.

20 CAR § 43-172. Hyperbaric suite.

(a) General.

(1) The number of treatment stations should be based upon the expected workload and may include several work shifts per day.

(2)(A) The location should offer convenient access for outpatients.

(B) Accessibility to the unit from parking and public transportation should be a consideration.

(b) Treatment areas.

(1) Hyperbaric chambers for multiple occupancy (Class A) should be installed in accordance with NFPA 99.

(2)(A) Hyperbaric chambers for individual patients (Class B) should be installed in accordance with NFPA 99 in a room or suite adequately sized to provide the following clearances:

- (i) Chamber and side wall, five feet (5');
- (ii) Between chambers, six feet (6'); and
- (iii) Between the chamber headboard and the wall, three feet (3').

(B) A minimum passage space of four feet (4') shall be provided at the foot of each chamber in addition to the required clearances for sliding patients' platforms in end-loading chambers.

(c) **Functional elements.** The following support spaces should be provided and may be shared with adjacent departments:

(1)(A) Patient waiting area.

(B) The area should:

- (i) Be out of traffic;
- (ii) Be under staff control; and
- (iii) Have seating capacity in accordance with the functional program.

(C) When the hyperbaric suite is routinely used for outpatients and inpatients at the same time, separate waiting areas should be provided with screening for visual privacy between the waiting areas;

(2) A control desk and reception area should be provided;

(3)(A) A holding area under staff control should accommodate inpatients on stretchers or beds.

(B) Stretcher patients should be out of the direct line of normal traffic.

(C) The patient holding area may be omitted for two (2) or fewer individual hyperbaric chamber units;

(4) Toilet rooms for the use of patients should be provided with direct access from the hyperbaric suite;

(5)(A) Dressing rooms for outpatients should:

- (i) Be provided; and

(ii) Include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables.

(B) At least one (1) dressing room should be provided to accommodate wheelchair patients;

(6) An appropriate room for individual and family consultation with referring physicians should be provided for outpatients;

(7)(A) A clean storage space should be provided for clean supplies and linens.

(B) Handwashing stations should be provided with hands-free operable controls.

(C) When a separate storage room is provided, it may be shared with another department when conveniently located;

(8)(A) A soiled holding room should be provided with waste receptacles and soiled linen receptacles.

(B) Storage for patients' belongings should be provided;

(9)(A) A housekeeping room should:

(i) Be provided; and

(ii) Contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(B) It should be located nearby;

(10)(A) Appropriate areas should be available for male and female personnel for staff:

(i) Clothing change area; and

(ii) Lounge.

(B) The areas should contain:

(i) Lockers;

(ii) Shower;

(iii) Toilet; and

(iv) Handwashing stations; and

(11) A waiting room, toilet with handwashing stations, drinking fountain, public telephone, and seating accommodations for waiting periods should be available or accessible to the unit.

(d) **Electrical requirements.**

(1) Grounding of hyperbaric chambers should be connected only to the equipment ground in accordance with NFPA 99 and NFPA 70.

(2) Additional grounds such as earth or driven grounds should not be permitted.

20 CAR § 43-173. Physical facilities — Helicopter landing area.

(a) Helicopter landing area, if provided, shall be documented.

(b) Safe planning for the helicopter service shall include the following:

(1) Plot plan showing the heliport for Department of Health files and inspection; and

(2) More than one (1) approach/departure route.

(c)(1) Service shall be as close to the emergency service at the hospital as can be accomplished safely.

(2) The department will consider that a helicopter landing area does exist upon repeated or regular use of a location.

(d)(1) See NFPA 418 for roof top heliports.

(2) **Note.**

(A) If there are wire obstacles, wire markers are available at no charge.

(B) They shall be picked up at the Division of Aeronautics.

20 CAR § 43-174. Physical facilities — Outpatient care facilities.

(a) **General considerations.**

(1) See 20 CAR § 43-142(a), physical facilities.

(2)(A) This section applies to the outpatient care unit licensed under the facility as a department and under the rule of the governing body.

(B) An outpatient care unit can be a:

- (i) Part of the facility; or
- (ii) Separate freestanding facility.

(C) An outpatient unit within the main facility building shall be located so outpatients do not traverse inpatient areas.

(3) The general standards set forth in the following sections shall apply to each of the items below:

- (A) Outpatient psychiatric centers;
- (B) Primary care outpatient centers; and
- (C) Diagnosis and/or treatment centers.

(4) Each element provided in the outpatient care facility shall:

- (A) Be described in the written functional program; and
- (B) Meet the requirements outlined herein as a minimum.

(b) **General construction considerations.** See 20 CAR § 43-142(a), physical facilities.

(c) **Site location, inspection, approval, and subsoil investigation.** See 20 CAR § 43-142(d) – (m), physical facilities.

(d) **Construction documents.** See 20 CAR § 43-142(k), physical facilities.

(e) **Codes and standards.** New/existing outpatient care facilities that do not meet the criteria of the NFPA, Life Safety Code for healthcare and/or ambulatory healthcare occupancies may be classified as a business occupancy as defined in LSC 101, Chapter 26 (new)/27 (existing) with exceptions noted within this part.

(f) **General requirements for outpatient care facilities.** As needed, the following elements shall be provided to satisfy the functional program:

(1)(A) Functional program.

(B) See 20 CAR § 43-142, physical facilities;

(2)(A) Parking.

(B) Each facility should provide adequate parking for staff and patients;

(3)(A) Patient privacy.

(B) Each facility design shall ensure patient audible and visual privacy and dignity during:

- (i) Interview;
- (ii) Examination;
- (iii) Treatment; and
- (iv) Recovery;

(4)(A) Administration and public areas.

(B) The following shall apply to each outpatient care facility described herein with additions and/or modification as noted for each specific type:

(i)(a) Entrance.

(b) Located at grade level and able to accommodate wheelchairs;

(ii) Public services shall include:

(a) Conveniently accessible wheelchair storage;

(b) A reception and information counter or desk;

(c)(1) Waiting space or spaces.

(2) Where an organized pediatric service is part of the outpatient care facility, provisions shall be made for separating pediatric and adult patients;

(d) Public toilets;

(e) Drinking fountain; and

(f) Public telephones;

(iii)(a) Interview space or spaces.

(b) Private interviews related to social services, credit, etc., shall be provided;

(iv) General or individual offices for business transactions, records, and administrative and professional staffs shall be provided;

(v) Clerical space or rooms for typing, clerical work, and filing, separated from public areas for confidentiality, shall be provided;

(vi) Multipurpose room or rooms equipped for visual aids shall be provided for:

(a) Conferences;

(b) Meetings; and

(c) Health education purposes;

(vii)(a) Special storage for staff personal effects with locking drawers or cabinets (may be individual desks or cabinets) shall be provided.

(b) Such storage shall be:

(1) Near individual workstations; and

(2) Staff-controlled.

(viii) General storage facilities for supplies and equipment shall be provided as needed for continuing operation; and

(ix) In new construction and renovation where hemodialysis or hemoperfusion are routinely performed, there shall be a separate water supply and a drainage facility that do not interfere with handwashing;

(5)(A) General purpose examination rooms.

(B) For medical and similar examinations, rooms shall have a minimum floor area of eighty square feet (80 sq. ft.) excluding:

(i) Vestibules;

(ii) Toilets; and

(iii) Closets.

(C) Room arrangement shall permit at least two feet eight inches (2' 8") of clearance at each side and at the foot of the examination table.

(D) A handwashing fixture and a counter or shelf space for writing shall be provided;

(6)(A) Special-purpose examination rooms.

(B) Rooms for special clinics such as eye, ear, nose, and throat examinations, if provided, shall be designed and outfitted to accommodate procedures and equipment used.

(C) A handwashing station and a counter or shelf space for writing shall be provided;

(7)(A) Treatment room or rooms.

(B) Rooms for diagnosis and/or treatment if provided shall have a minimum floor area of one hundred twenty square feet (120 sq. ft.) excluding:

(i) Vestibule;

(ii) Toilet; and

(iii) Closets.

(C) The minimum room dimension shall be ten feet (10').

(D) A handwashing fixture and counter or shelf for writing shall be provided;

(8)(A) Observation room or rooms.

(B) Observation rooms for the isolation of suspect or disturbed patients shall:

(i) Have a minimum floor area of eighty square feet (80 sq. ft.); and

(ii) Be convenient to a nurse or control station.

(C) This is to:

(i) Permit close observation of patients; and

(ii) Minimize possibilities of patients':

(a) Hiding;

(b) Escape;

(c) Injury; or

(d) Suicide.

(D) An examination room may be modified to accommodate this function.

(E) A toilet room with lavatory should be immediately accessible;

(9)(A) Control station.

(B) A work counter, communication system, space for supplies, and provisions for charting shall be provided;

(10)(A) Medication distribution station.

(B) This may be a part of the control station and shall include:

(i) A work counter;

(ii) A sink;

(iii) A refrigerator; and

(iv) Locked storage for biologicals and medications;

(11)(A) Clean holding.

(B) A separate room or closet for storing clean and sterile supplies shall be provided.

(C) This storage shall be in addition to that of cabinets and shelves;

(12)(A) Soiled holding.

(B) Provisions shall be made for separate collection, storage, and disposal of soiled materials;

(13)(A) Sterilizing facilities.

(B) A system for sterilizing equipment and supplies shall be provided if required by the narrative program;

(14)(A) Wheelchair storage space.

(B) Such storage shall be out of the direct line of traffic;

(15)(A) The need for and number of required airborne infection isolation rooms shall be determined by an infection control risk assessment.

(B) When required, the airborne infection isolation room or rooms shall comply with the general requirements of 20 CAR § 43-143(d);

(16)(A) Imaging suite.

(B) See 20 CAR § 43-151, physical facilities — imaging suite;

(17)(A) Laboratory.

(B) See 20 CAR § 43-154, physical facilities — laboratory services;

(18)(A) Rehabilitation services.

(B) See 20 CAR § 43-175, physical facilities — rehabilitation facilities;

(19)(A) Environmental services, safety services, physical environment.

(B) See 20 CAR § 43-142, physical facilities;

(20)(A) Staff facilities.

(B) See 20 CAR § 43-165, physical facilities — engineering service and equipment areas;

(21)(A) Waste processing services.

(B) See 20 CAR § 43-166, physical facilities — waste processing services;

(22)(A) Social spaces/group therapy.

(B) See Rules for Hospitals and Related Institutions in Arkansas, 20 CAR § 41-181(f)(3), physical facilities — psychiatric hospitals and alcohol/drug abuse inpatient treatment centers;

(23) Details shall comply with the following standards:

(A)(i) Minimum patient corridor width shall be five feet (5').

(ii) Staff-only corridors may be forty-four inches (44") wide;

(B)(i) Each building shall have two (2) exits that are remote from each other.

(ii) Other details relating to exits and fire safety shall comply with:

(a) NFPA 101; and

(b) The standards outlined herein;

(C)(i) Items such as drinking fountains, telephone booths, vending machines, etc., shall not:

(a) Restrict corridor traffic; or

(b) Reduce corridor width below the minimum.

(ii) Out-of-traffic storage space for portable equipment shall be provided;

(D)(i) The minimum nominal door width for patient use shall be three feet (3').

(ii) If the outpatient facility services hospital inpatients, the minimum nominal width of doors to rooms used by hospital inpatients transported in beds shall be three feet eight inches (3' 8");

(E)(i) Doors, sidelights, borrowed lights, and windows glazed to within eighteen inches (18") of the floor shall be constructed with:

(a) Safety glass;

(b) Wired glass; or

(c) Similar materials.

(ii) Glazing materials used for shower doors and bath enclosures shall be safety glass or plastic;

(F) Threshold and expansion joints covers shall be flush with the floor surface;

(G) Handwashing stations shall be located and arranged to permit proper use and operation;

(H) Provisions for hand drying shall be included at all handwashing facilities;

(I) Radiation protection for X-ray and gamma ray installations shall be in accordance with the rules of the Department of Health; and

(J) The minimum ceiling height shall be seven feet eight inches (7' 8");

(24) Finishes shall comply with the following:

(A) Cubicle curtains and draperies shall:

(i) Be noncombustible or flame-retardant; and

(ii) Pass both the large-scale and small-scale tests required by NFPA

701;

(B) The flame spread and smoke development ratings of finishes shall comply with NFPA 101Chapter 38;

(C)(i) Floor materials shall be:

(a) Readily cleanable; and

(b) Appropriately wear-resistant.

(ii) In all areas subject to wet cleaning, floor materials shall not be physically affected by liquid germicidal and cleaning solutions.

(iii) Floors subject to traffic while wet, including showers and bath areas, shall have a nonslip surface;

(D) Wall finishes:

(i) Shall be washable; and

(ii) In the proximity of plumbing fixtures; shall be smooth and water-resistant;

(E) Wall bases in areas frequently subject to wet cleaning methods shall be:

(i) Monolithic and coved with the floor;

(ii) Tightly sealed to the wall; and

(iii) Constructed without voids; and

(F)(i) Floor and wall areas penetrated by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects.

(ii) Joints of structural elements shall be similarly sealed;

(25)(A) Provision for disasters.

(B) See 20 CAR § 43-141, physical environment; and

(26)(A) Mechanical, plumbing, and electrical.

(B) Small outpatient clinics that provide space and equipment serving four (4) or fewer direct patient care workers at one (1) time shall comply with the following minimum requirements:

(i) Emergency lighting shall be connected to rechargeable backup batteries as a means of emergency illumination; and

(ii) A protected premises fire alarm system as defined in Chapter 3, NFPA 72 is required.

(C) Large outpatient facilities that provide space and equipment for more than four (4) direct patient care workers at one (1) time shall comply with the following minimum requirements:

(i) Emergency lighting and power shall be provided in accordance with NFPA 99, NFPA 101, and NFPA 110;

(ii) Any fire alarm system shall be:

(a) As required by NFPA 101; and

(b) Installed per NFPA 72;

(iii) The installation, testing, and certification of nonflammable medical gas and air systems shall comply with the requirements of NFPA 99;

(iv) Clinical vacuum system installed shall be in accordance with NFPA 99;

(v) All electrical material and equipment shall be installed, tested, and certificated in accordance with NFPA 70 and NFPA 99;

(vi) The mechanical system shall comply with 20 CAR § 43-169, physical facilities — mechanical requirements, with the following exceptions:

(a) Redundant space heating and water heating capability are not required unless required by the written functional program;

(b) Ducted return air systems are not required unless required by the written narrative; and

(c) Standby fuel for space and water heating is not required;

(vii)(a) A nurses' emergency call system shall be provided for all patient use at each patient:

(1) Toilet;

(2) Bath;

(3) Sitz bath; and

(4) Shower room.

(b) This system shall be accessible to a patient lying on the floor.

(c) Inclusion of a pull cord shall satisfy this standard; and

(viii) Fire extinguisher or extinguishers shall be provided and be easily accessible per NFPA requirements.

20 CAR § 43-175. Physical facilities — Rehabilitation facilities.

(a) General considerations.

(1) Rehabilitation facilities may be organized under:

(A) Hospitals (organized departments of rehabilitation);

(B) Outpatient clinics;

(C) Rehabilitation centers; and

(D) Other facilities designed to serve either single-disability or multiple-disability categories including but not limited to:

(i) Cerebrovascular;

(ii) Head trauma;

(iii) Spinal cord injury;

(iv) Amputees;

- (v) Complicated fractures;
- (vi) Arthritis;
- (vii) Neurological degeneration;
- (viii) Genetic; and
- (ix) Cardiac.

(2) In general, rehabilitation hospitals shall have:

- (A) Larger space requirements than general hospitals;
- (B) Longer lengths of stay; and
- (C) Fewer institutional and more residential environments.

(b) **General construction considerations.** See 20 CAR § 43-142(a), physical facilities.

(c) **Site location, inspection, approval, and subsoil investigation.** See 20 CAR § 43-142(d) – (m), physical facilities.

(d) **Construction documents.** See 20 CAR § 43-142(k), physical facilities.

(e) **Codes and standards.** See 20 CAR § 43-142(a) and (o), physical facilities.

(f) **Functional units and service areas.**

(1) **Required units.** Each rehabilitation facility shall:

- (A) Contain a medical evaluation unit; and
- (B) Provide the following service areas, if the services are not otherwise

conveniently accessible to the facility and appropriate to program functions:

- (i) Psychological services;
- (ii) Social services;
- (iii) Vocational services;
- (iv) Patient dining, recreation, and day spaces;
- (v) Dietary;
- (vi) Personal care facilities;
- (vii) Space for teaching activities of daily living;
- (viii) Administration department;
- (ix) Medical records;
- (x) Engineering service and equipment areas;

- (xi) Laundry services;
- (xii) Housekeeping rooms;
- (xiii) Employees' facilities;
- (xiv) Nursing unit;
- (xv) Physical therapy;
- (xvi) Occupational therapy; and
- (xvii) Speech and hearing.

(2) Optional units.

(A) The following special services areas, if required by the functional program, shall be provided as outlined in this part.

(B) The sizes of the various departments will depend upon the services to be provided:

- (i) Sterilizing facilities;
- (ii) Prosthetics and orthotics;
- (iii) Dental;
- (iv) Radiology;
- (v) Pharmacy;
- (vi) Laboratory;
- (vii) Home health;
- (viii) Outpatient services; and
- (ix) Therapeutic pool.

(g) Evaluation unit.

(1) Office or offices for personnel.

(2) Examination rooms.

(A) The rooms shall have a minimum floor area of one hundred forty square feet (140 sq. ft.) excluding such spaces as the vestibule, toilet, closet, and work counter, whether fixed or movable.

(B) The minimum room dimension shall be ten feet (10').

(C) The room shall contain a:

- (i) Lavatory or sink equipped for handwashing;

- (ii) Work counter and storage facilities; and
- (iii) Desk, counter, or shelf space for writing.

(3) Evaluation rooms.

(A) The room areas shall be arranged to:

- (i) Permit appropriate evaluation of patient needs and progress; and
- (ii) Determine specific programs of rehabilitation.

(B) Rooms shall include:

- (i) A desk and work area for the evaluators;
- (ii) Writing and workspace for patients; and
- (iii) Storage for supplies.

(C) Where the facility is small and workload light, evaluation may be done in the examination room.

(4) Laboratory facilities.

(A) Facilities shall be provided within the rehabilitation department or through contract arrangement with a nearby hospital or laboratory service for:

- (i) Hematology;
- (ii) Clinical chemistry;
- (iii) Urinalysis;
- (iv) Cytology;
- (v) Pathology; and
- (vi) Bacteriology.

(B) If these facilities are provided through contract, the following minimum laboratory services shall be provided in the rehabilitation facility:

(i) Laboratory work counter or counters with a sink and gas and electric service;

- (ii) Handwashing stations;
- (iii) Storage cabinet or cabinets or closet or closets; and
- (iv)(a) Specimen collection facilities.

(b) Urine collection rooms shall be equipped with a water closet and lavatory.

(c) Blood collection facilities shall have space for a chair and work counter.

(5) **Imaging facilities.** Imaging facilities, if required by the functional program, shall be in accordance with 20 CAR § 43-151, physical facilities — imaging suite.

(h) **Psychological service.** An office or offices and workspace for testing, evaluation, and counseling shall be provided.

(i) **Social service.** Office space or spaces for private interviewing and counseling shall be provided.

(j) **Vocational services.** An office or offices and workspace for vocational training, counseling, and placement shall be provided.

(k) **Dining, recreation, and day spaces.** The following standards shall be met for patient dining, recreation, and day spaces (areas may be in separate or adjoining spaces):

(1) Inpatient and residents shall have a total of fifty-five square feet (55 sq. ft.) per bed;

(2)(A) Outpatients.

(B) If dining is part of the daycare program, a total of fifty-five square feet (55 sq. ft.) per person shall be provided.

(C) If dining is not part of the program, at least thirty-five square feet (35 sq. ft.) per person shall be provided for recreation and day spaces; and

(3) Storage spaces shall be provided for recreation equipment and supplies.

(l) **Dietary department.** See 20 CAR § 43-158, physical facilities — dietary facilities.

(m) **Personal care unit for inpatients.**

(1) A separate room with appropriate fixtures and utilities shall be provided for patient grooming.

(2) The activities for daily living unit may serve this purpose.

(n) **Activities for daily living unit.**

(1) An area for teaching daily living activities shall be provided.

- (2) It shall include a:
 - (A) Bedroom;
 - (B) Bath;
 - (C) Kitchen; and
 - (D) Space for training stairs.
- (3) Equipment shall be functional.
- (4) The bathroom shall be in addition to other toilet and bathing requirements.
- (5) The daily living area shall be similar to a residential environment for the purpose of facilitating the patient's skill for daily living.

(o) **Administration department and medical records.** See 20 CAR § 43-159, physical facilities — administration and public areas.

(p) **Engineering service and equipment areas.** See 20 CAR § 43-165, physical facilities — engineering service and equipment areas.

(q) **Laundry services.** See 20 CAR § 43-163, physical facilities — linen services.

(r) **Housekeeping rooms.** See 20 CAR § 43-164, physical facilities — cleaning and sanitizing carts, employee facilities, and environmental closets.

(s) **Employee facilities.** See 20 CAR § 43-165, physical facilities — engineering service and equipment areas.

(t) **Nursing.**

(1) The nursing units for rehabilitation facilities shall follow the standards as described in 20 CAR § 43-143, physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease, with the following exceptions:

(A)(i) Patient rooms.

(ii) Minimum areas exclusive of toilet rooms, closets, lockers, wardrobes, alcoves, or vestibules shall be:

(a) One hundred forty square feet (140 sq. ft.) in single-bed rooms; and

(b) One hundred twenty-five square feet (125 sq. ft.) per bed in semiprivate rooms;

(B)(i) Each patient shall have access to a toilet room without having to enter the general corridor area.

(ii) One (1) toilet room shall serve no more than:

(a) Four (4) beds; and

(b) Two (2) patient rooms.

(iii) The toilet room shall contain a:

(a) Water closet;

(b) Handwashing fixture; and

(c) Tub and/or shower.

(iv) The handwashing fixture may be omitted from a toilet room that serves single-bed and two-bed rooms if each such patient's room contains a handwashing fixture.

(v) Each toilet room shall be of sufficient size to ensure that wheelchair users and staff shall have access; and

(C)(i) Each patient shall have access to a wardrobe, closet, or locker with minimum clearance of one foot ten inches by one foot eight inches (1' 10" x 1' 8").

(ii) A clothes rod and adjustable shelf shall be provided.

(2) Nursing unit service areas shall follow the standards described in 20 CAR § 43-143, physical facilities — patient accommodations — adult medical, surgical — communicable or pulmonary disease, with the following exceptions:

(A)(i) Patient bathing facilities.

(ii) At least one (1) island-type bathtub and/or gurney shower shall be provided in each nursing unit.

(iii) Each tub and/or shower shall be in an individual room or privacy enclosure that provides space for:

(a) The private use of bathing fixtures;

(b) Drying and dressing; and

(c) A wheelchair and an assistant.

(iv) Showers in central bathing facilities shall be:

(a) At least four feet square (4 sq. ft.);

(b) Curb-free; and

(c) Designed for use by a wheelchair patient;

(B)(i) At least one (1) room on each floor containing a nursing unit shall be provided for toilet training.

(ii) It shall be accessible from the nursing corridor.

(iii) A minimum clearance of three feet (3') shall be provided at the front and at each side of the water closet.

(iv) The room shall also contain a lavatory; and

(C)(i) Handrails shall be provided on both sides of corridors used by patients.

(ii) A clear distance of one and one-half inches (1 1/2") shall be provided between the handrail and the wall, and the top of the rail shall be thirty-four inches (34") minimum and thirty-six inches (36") maximum above the floor.

(iii) Exceptions for height shall be for special care areas such as those serving children.

(u) **Sterilizing facilities.** See 20 CAR § 43-164, physical facilities — cleaning and sanitizing carts, employee facilities, and environmental closets.

(v) **Rehabilitation therapy.** See 20 CAR § 43-155, physical facilities — rehabilitation therapy department.

(w) **Pharmacy unit.** See 20 CAR § 43-157, physical facilities — pharmacy.

(x) **Details and finishes.** See 20 CAR § 43-167, physical facilities — details and finishes.

(y) **Design and construction, including fire-resistant standards.** See 20 CAR § 43-168, physical facilities — construction, including fire-resistive requirements.

(z) **Waste processing services.** See 20 CAR § 43-166, physical facilities — waste processing services.

(aa) **Elevators.** See 20 CAR § 43-171, physical environment — electrical standards.

(bb) **Mechanical, plumbing, and electrical standards.** See 20 CAR §§ 43-170, 43-171, 43-174(f)(22).

Appendix A. No Patient Left Alone Act

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/332/20CARpt.43AppendixA.pdf>

Appendix B. Table 1 - Filter Efficiencies for Central Ventilation and Air Conditioning Systems in Health Care Facilities

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/333/20CARpt.43Table1.pdf>

Appendix C. Table 2 - Sound Transmission Limitations in Health Care Facilities

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/334/20CARpt.43Table2.pdf>

Appendix D. Table 3 - Temperature and Relative Humidity Requirements

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/335/20CARpt.43Table3.pdf>

Appendix E. Table 4 - Ventilation, Medical Gas, and Air Flow Requirements in Health Care Facilities

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Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/336/20CARpt.43Table4.pdf>

Appendix F. Table 5 - Final Occupancy Inspection Check List

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/337/20CARpt.43Table5.pdf>

Appendix G. Table 6 - Dog Behavioral Screening Exam

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/339/20CARpt.43Table6.pdf>

Appendix H. Table 7 - Dog History

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/340/20CARpt.43Table7.pdf>

Appendix I. Table 8 - Record Retention Time Frames

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/341/20CARpt.43Table8.pdf>

Appendix J. Table 9 - Required Temperatures

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Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/342/20CARpt.43Table9.pdf>

Appendix K. Table 10 - Central Station Outlets for Oxygen, Vacuum (Suction), and Medical Air Systems in Hospitals and Related Institutions

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/343/20CARpt.43Table10.pdf>

Appendix L. Table 11 - Verbal Orders

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/344/20CARpt.43Table11.pdf>

Appendix M. Table 12 - Third Party Reprocessing Of Single Use Items

Link:

<https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/338/20CARpt.43Table12.pdf>