EXHIBIT C

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

SUBJECT: Control of Source Ionizing Radiation

DESCRIPTION: The Radiation Control Section regulates the possession and use of x-ray machines, accelerators, and radioactive material in the state. Revisions to x-ray machine and accelerator regulations are drawn primarily from the nationally recognized Conference of Radiation Control Program Directors' Suggested State Regulations. Revisions to radioactive material regulations are driven by agreement with the U.S. Nuclear Regulatory Commission (NRC). The state, as an Agreement State, is expected to have regulations that are compatible with NRC regulations. To maintain this compatibility, one NRC regulation amendment (as well as some general clean-up) is being addressed, as listed below:

1. Revisions to definitions of "construction" and "commencement of construction" due to NRC regulation amendment RATS 2011-2, "Licenses, Certifications, and Approvals of Materials Licensees."

2. Revisions to Section 3, "Standards for Protection Against Radiation," concerning Appendix A to Section 3, Appendix B to Section 3, RH-1210, RH-1303, and the RH-1400's (deletion of a table and related regulations that have been superseded by other current regulations, to maintain compatibility with the NRC; and other clean-up).

3. Removal of individual letter/number designations from definitions throughout the regulations; and general clean-up of some definitions.

4. Revision of current accelerator licensing and radiation safety requirement regulations including Section 6, "Particle Accelerators," and related regulations in Part I, "Radiation Safety Requirements for Industrial Radiographic Operations," and Part J, "Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies," of Section 3 (general clean-up and clarification; addition of licensing requirements comparable to those used with radioactive material licenses; updating of radiation safety provisions; addition of survey meter operability and calibration requirements previously handled in licensing).

5. Addition of a new Section 11, "Therapeutic Radiation Machines," that will address therapeutic uses of x-ray machines (<500 kV_, medical accelerators (≥500 kV/keV), and electronic brachytherapy devices. The new section will update and make more succinct existing requirements found in RH-1607, 1608, and the 5500's. These sections will be deleted.

6. Revisions to the initial registration requirements and reporting of changes regarding registration of x-ray machines and electronic brachytherapy devices (registration required prior to operation of the machine/device, designation of a Radiation Safety Officer, notification of the department prior to changes that render registration no longer accurate).

PUBLIC COMMENT: This rule underwent two public comment periods during which two public hearings were held. The first public comment period resulted in the Department revising the proposed rule. Because of these revisions, the Department decided to have a second public comment period and a second public hearing.

First Public Comment Period: A public hearing was held June 10, 2014. The public comment period expired June 10, 2014. The Department received the following public comments:

Colleague of Dr. Miranda Childs Bebee

COMMENT: The first change is to section RH-21 1-4 Initial Registration and requires a new pano or other X-ray machine to be registered BEFORE it can be used. Current rules allow 30 days for registration. When a new machine is installed, it is ready for patient treatment and having to wait for the registration certificate to be generated by the ADH will delay patient treatment. In the case of a panoramic film where cancers of the jaw are often first detected, this delay in diagnosis could have significant health consequences.
RESPONSE: The proposed RH-21 has been revised to reflect registration within 30 days of acquisition. Certain machine uses are given that must be authorized by the Department prior to operation.

COMMENT: The second change is to section RH-26 1-5 (pg 29) deletes the 10 day reporting period for changes to x-ray machines and requires the ADH be notified BEFORE any changes are made. This is simply unnecessary as these changes usually include the retirement of old equipment which is usually recycled or given to a charitable clinic often outside the US.
RESPONSE: The proposed RH-26 has been revised to reflect notification of the Department regarding registration changes within 10 days of the change. Changes regarding certain machine uses must be reported prior to the change being made.

Arthur Wolover, CRNA, APRN

COMMENT: The regulation of concern can be found on Page 1-4: PART C. REGISTRATION OF RADIATION MACHINES RH-21 c. In the interest of clarity and accuracy, and to reflect current CRNA/APRN practice in Arkansas, we believe that the State Board of Nursing should be added to those Boards cited and enclosed in parentheses. The paragraph would then read: "A practitioner, licensed by the respective state board of examiners (i.e., state medical board, state dental board, state chiropractic board, state podiatric board, **state nursing board**), responsible for directing the operation of radiation machines . . . " CRNAs, as do other Advanced Practice Registered Nurses (APRNs), fall within the definition of "A practitioner . . . responsible for directing . . . " when they order Xrays, for example, in the regular course of their practices.

The American Association of Nurse Anesthetists' document, Scope of Nurse Anesthesia Practice, within the section Anesthesia Practice, states "CRNAs . . . order and evaluate diagnostic tests; . . . " and, "CRNAs plan and initiate anesthetic techniques, including general, regional, local, and sedation. Anesthetic techniques may include the use of

ultrasound, **fluoroscopy**, and other technologies for diagnosis and care delivery, and to improve patient safety and comfort."

We believe that the regulation, as written, is ambiguous as to its intent when listing the various boards, whether for purposes of illustration or for purposes of exclusivity. In order to remove that ambiguity, we would ask that the above language be substituted as indicated within the proposed regulation.
RESPONSE: The applicant/registrant having physical possession or control of a radiation machine capable of producing radiation in the state of Arkansas, or an individual duly authorized to act for and on his behalf, is who must sign the registration application. This intent is clarified in the proposed RH-21.

Second Public Comment Period: A public hearing was held September 2, 2014. The public comment period expired September 2, 2014. The Department received no public comments.

The proposed effective date for the rule is November 14, 2014.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: Ark. Code Ann. § 20-21-217 provides that the Department must require in its licensing and rules "applicable standards promulgated by the agency which are equivalent to or more stringent than standards adopted and enforced by the United States Nuclear Regulatory Commission".

Ark. Code Ann. § 20-21-207 requires the Department to develop programs and rules to regulate the control of ionizing radiation.

Ark. Code Ann. §§ 20-21-208 and 20-21-214 give the Department authority to "require registration or licensing of other sources of ionizing radiation".

Ark. Code Ann. § 20-21-213 requires the Department to promulgate rules "for general or specific licensing of accelerator-produced material, by-product material, source material, special nuclear material, or devices or equipment utilizing such material". Ark. Code Ann. § 20-21-213 provides in addition that this rule "shall provide for amendment, suspension, or revocation of licenses".

Ark. Code Ann. § 20-21-217 sets out a fee regime the Department may charge "associated with licensing and registration of sources of ionizing radiation. Ark. Code Ann. § 20-21-217 also requires the Department to charge a ten percent (10%) late fee. Ark. Code Ann. § 20-21-217 also provides a fee regime "associated with X-ray registrations.

Ark. Code Ann. § 20-21-204 provides that the Department may assess a civil penalty not to exceed five thousand dollars ($5,000) to a person who violates any licensing or

registration requirement issued by the Department or who violates the provisions of Ark. Code Ann. § 20-21-201 et seq. or the Department's rules.

10 CFR pts. 1-50 provide the federal regulatory structure of the Nuclear Regulatory Commission.

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY Arkansas Department of Health

DIVISION Center for Health Protection

DIVISION DIRECTOR Donnie Smith

CONTACT PERSON Bernard Bevill

ADDRESS 4815 W. Markham, Slot 30, Little Rock, AR 72205-3867

PHONE NO. (501) 661-2301 **FAX NO.** (501) 280-4407 **E-MAIL** bernard.bevill@arkansas.gov

NAME OF PRESENTER AT COMMITTEE MEETING Robert Brech

PRESENTER E-MAIL robert.brech@arkansas.gov

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? Rules and Regulations for Control of Source Ionizing Radiation

2. What is the subject of the proposed rule? These Regulations pertain to the use of radioactive material in the state of Arkansas. As an agreement state with the U.S. Nuclear Regulatory Commission (NRC), Arkansas must have regulations that are compatible with the NRC. The proposed changes make our current rules NRC compatible. Accelerator/therapeutic radiation machine regulations are also being updated.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☒ No ☐

If yes, please provide the federal rule, regulation, and/or statute citation. Section 274 of Atomic Energy Act, 1954

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes ☐ No ☒

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

When does the emergency rule expire? _____

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes ☐ No ☐

5. Is this a new rule? Yes ☐ No ☒
If yes, please provide a brief summary explaining the regulation. _____

Does this repeal an existing rule? Yes ☐ No ☒
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

Is this an amendment to an existing rule? Yes ☒ No ☐
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. A.C.A. 20-21-203--217

7. What is the purpose of this proposed rule? Why is it necessary? One purpose of the proposed rules is to make the current Arkansas Rules compatible with the NRC. The changes to the rules also reflect the current state of radioactive material regulations within the NRC regulated states and other Agreement States. Last, the regulations will improve general health and safety for the use of radioactive material. Accelerator/therapeutic radiation machine regulations are also being updated.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). www.healthy.arkansas.gov

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐
If yes, please complete the following:

Date: September 2, 2014
Time: 10:00 a.m.
Place: 5800 West 10th Street, Room 906, Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
September 2, 2014

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
November 14, 2014

12. Do you expect this rule to be controversial? Yes ☐ No ☒
If yes, please explain. _____

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

Medical physicists for accelerators

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION Center for Health Protection
PERSON COMPLETING THIS STATEMENT Angela Minden
TELEPHONE NO. (501) 661-2528 **FAX NO.** (501) 280-4407 **EMAIL:** angela.minden@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Rules and Regulations for Control of Sources of Ionizing Radiation

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 an agency is proposing a more costly rule, please state the following:

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

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

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;

   (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.

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		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	

Total	0	Total	0

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

Current Fiscal Year		Next Fiscal Year	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	0	Total	0

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

Current Fiscal Year	Next Fiscal Year
$ 0	$ 0

6. What is the total estimated cost by fiscal year to state, county, and 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
$ 0	$ 0

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.