

EXHIBIT E

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION (3105)

SUBJECT: Rules and Regulations for Control of Sources of Ionizing Radiation

DESCRIPTION: The Radiation Control Section is initiating the process for the revision of the Arkansas State Board of Health Rules and Regulations for Control of Sources of Ionizing Radiation. The Section regulates the possession and use of x-ray machines, accelerators, and radioactive material in the State of Arkansas. Revisions to radioactive material regulations are driven by our agreement with the U.S. Nuclear Regulatory Commission (NRC). The State of Arkansas, as an Agreement State, is expected to have regulations that are compatible with NRC regulations. In order to maintain this compatibility, the following NRC regulation amendments are being addressed, as listed below.

- **Domestic Licensing of Special Nuclear Material –Written Reports and Clarifying Amendments:**

The objective of this rule is to amend current regulations related to reportable safety events involving special nuclear material. This rule increases the time NRC licensees are allowed to submit a written follow-up report from 30 days to within 60 days after the initial report of an event, updates the reporting framework for certain situations, and removes redundant reporting requirements. (*Section 2*)

- **Transportation Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements:**

The purpose of this rule regards conforming changes to the NRC’s regulations based on the IAEA’s 2009 standards for the international transportation of radioactive material and maintaining consistency with the U.S. DOT regulations. In addition, this amendment re-establishes restrictions on materials that qualify for the fissile material exemption, clarifies requirements, updates administrative procedures, and makes editorial changes. (*Section 4*)

- **Miscellaneous Corrections, 10 CFR Parts 37 and 40:**

The objective of this rule is make miscellaneous corrections involving correcting references, typographical errors, and misspellings. (*Sections 2 and 12*)

- **Miscellaneous Corrections, 10 CFR Parts 19, 20, 30, 32, 37, 40, 61, 70, 71, and 150:**

The objective of this rule is to make miscellaneous corrections including renaming the Office of Information Services; capitalizing the word Tribe, Tribes, and Tribal; correcting a Web site address; and removing a Federal Register notice requirement. (*Sections 2, 3, 4, and 12*)

Also, the following sections not in conjunction with a particular NRC regulation amendment have been added, revised, or deleted in keeping with NRC compatibility. Some general clean-up is being performed as well.

RH-107.	Deliberate Misconduct
RH-200.	Definition of “decommission” and “sealed source”
RH-301.a.4.	Radioactive Material Other Than Source Material; exempt concentrations
RH-401.a.	General Licenses – Source Material; small quantities of source material

RH-405.c.	General Licenses – Source Material; certain industrial products or devices
RH-402.c.9.A. and 13.A.; 15; and e.	General Licenses – Radioactive Material Other Than Source Material; certain detecting, measuring, gauging, or controlling devices...; Footnote 6 to Section 2
RH-402.f.	Luminous safety devices in aircraft
RH-402.g.	Calibration and reference sources
RH-402.h.	Ownership of radioactive material
RH-402.i.	Ice detection devices
RH-402.j.	Products containing radium-226
RH-402.m.	Ownership of special nuclear material
RH-404.a.	General Requirements for the Issuance of Specific Licenses
RH-405.e.4.A. and B.	Licensing of the manufacture or initial transfer of devices to persons generally licensed under RH-402.a.
RH-405.g.	Licensing of the introduction of radioactive material into products in exempt concentrations
RH-409.c.	Specific Terms and Conditions of Licenses
RH-410.e.1. and j.1.	Expiration and Termination of Licenses and Decommissioning of
RH-501.a. and d.	Conditions of Transfer
RH-600.d. and e.	Records
RH-601.	Reporting Requirements
RH-1212.	Leak Tests
RH-1303.b.4. and 5.	Posting requirements
RH-1310.a.	Exemptions to Labeling Requirements
RH-1500.a.	Records; general provisions
RH-1500.d.	Determination of prior occupational dose; Footnote 6 to
RH-1500.f.1.	Records of individual monitoring results; recordkeeping
RH-1500.f.5.	Records of individual monitoring results (records of dose to embryo/fetus)
RH-1500.j.	Records of tests for leakage and/or contamination of sealed
RH-1500.n.1.A.	Record retention periods
RH-1501.	Reports of Theft or Loss of Sources of Radiation
RH-1502.	Notification of Incidents
RH-1504.	Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits
RH-1505.b.	Reports to individuals of exceeding dose limits
RH-1508.	Reports of Leaking Sealed Sources
RH-1513.f. and g.	Reports of Transactions Involving Nationally Tracked Sources
RH-1800.c.	Definition of “radiographer instructor”
RH-1801.f.3.A. and k.	Equipment Control; leak testing and replacement of sealed sources;

RH-1802.b.2.A. and 3.A.	Personnel Radiation Safety Requirements for Radiographers and
RH-1802.g.	Personnel Radiation Safety Requirements for Radiographers and
RH-1803.f.	Precautionary Procedures in Radiographic Operations; specific requirements for radiographic personnel performing industrial radiography
RH-1935.a.	Leak testing of sealed sources; testing and recordkeeping requirements
RH-2804.f.	Notifications and Reports to Individuals
RH-3100.	Definition of “Certificate of Compliance (CoC)”
RH-3305.a. and b.	General License: Fissile Material
RH-3306.a. and b.	General License: Plutonium-Beryllium Special Form Material
RH-3602.	Quality Assurance Program
RH-3603.	Handling, Storage, and Shipping Control
RH-3604.	Inspection, Test, and Operating Status
RH-3605.	Nonconforming Materials, Parts, or Components
RH-3606.	Corrective Action
RH-3608.	Audits
RH-7021.a.	Performance Criteria for Sealed Sources; requirements
RH-7033.a. and b.	Irradiator Pools
RH-7039. preamble	Design Requirements
RH-7041. preamble	Construction Monitoring and Acceptance Testing
RH-7059.c.	Detection of Leaking Sources
RH-7083.b.	Reports
RH-11005.	Definition of “security zone”
RH-11043.d.7.	General Security Program Requirements; protection of
RH-11041.a.3.	Security Program; applicability
RH-11075.a.	Preplanning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material

PUBLIC COMMENT: A public hearing was held on March 8, 2017. The public comment period expired on March 8, 2017. The department received the following comments from the U.S. Nuclear Regulatory Commission (NRC):

Comment: Arkansas regulations in RH-3301.b., 3304.b., 3305.b., 3306.b., 3600.b.,c., and 3602.a. should refer to their Agency and not to the NRC. Also, cross-references should be to AR regulations, as this requirement applies to the AR licensee's quality assurance program.

Response: These regulations will maintain current rule language that lists the Department and its requirements as governing Arkansas licensee quality assurance programs instead of proposed language that indicates NRC has the authority.

Comment: Arkansas regulation RH-3301.c. should contain the AR point of contact.

Response: Paragraph c.3. of the "General License for NRC- Approved Packages" states the third requirement that each Arkansas general licensee must do and that is register with the NRC (not Arkansas) before first use of the package. Registration with the NRC is per U.S. DOT 49 CFR 173.471(a) and is for any offeror of a Type B(U), Type B(M), or fissile material package that has been approved by the NRC. Paragraph c.3. will retain proposed language with a correction to the NRC Division name listed.

Comment: Arkansas needs to include the phrase "design, fabrication, and assembly records; results of reviews...and the action taken in connection with any deficiencies noted" in RH-3506.c. after the reference to RH-3502.

Response: Paragraph c. will maintain current rule language that lists these records to be maintained by the licensee as evidence of quality of packaging, instead of proposed language that removes this list.

Comment: Arkansas may remove references in Section 4 to certificate holders and applicants for Certificates of Compliance due to these being NRC licensees and therefore not regulated by the State of Arkansas.

Response: References to certificate holders and applicants for Certificates of Compliance will be stricken from RH-3600.b., 3601.a., 3602.a.,b.,d.,e., and 3603.-3608. leaving "licensee."

Comment: Arkansas needs to remove the sentence "Each certificate holder and applicant for a package approval is responsible for satisfying the quality assurance requirements that apply to design, fabrication, testing, and modification of packaging subject to this Part." from RH-3600.a. as this applies to NRC certificate holders and applicants, or otherwise modify this paragraph to meet the essential objectives.

Response: Explanatory language will be added to paragraph a., "Purpose," in order to clarify agency authorities. There will be no change in requirements.

Comment: Arkansas may remove references in paragraphs b. and c. of RH-3602. to certificate holders and applicants for Certificates of Compliance due to these being NRC licensees and therefore not regulated by the State of Arkansas, or otherwise modify these paragraphs to meet the essential objectives.

Response: Explanatory language will be added to paragraphs b. and c. in order to better direct Arkansas licensees. There will be no change in requirements.

Comment: Arkansas needs to reference their Agency and not the NRC in RH-3602.e. as the State would approve their licensee's quality assurance program. Also, the cross-reference in paragraph e. should be to AR regulations, as this requirement applies to the AR licensee's quality assurance program.

Response: This regulation will indicate that Arkansas quality assurance programs, including changes, are approved by the Department pursuant to its requirements, like that of Comment 1.

Comment: In RH-600.a.2., Arkansas omits the phrase, "until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement." As written, AR's regulation is less restrictive than 10 CFR 40.61(a)(2) as it only requires the licensee to retain the records for three years, and not until the license is terminated. AR needs to add their equivalent regulation as indicated above.

Response: RH-600.a.2. as it currently reads was approved by the NRC in Department regulations effective July 1, 2002. The retention period for radioactive material transfer records was also approved by the NRC on May 12, 2010, as part of the Conference of Radiation Control Program Director's Suggested State Regulations. Arkansas does not have the authority to regulate the same types of Part 40, "source material," licensees that the NRC does (e.g., uranium mills, enrichment facilities, and UF₆ production facilities); therefore, three years is an adequate retention period for Arkansas source material licensees. This retention period meets the essential objective.

Comment: In RH-11027.c.1., Arkansas needs to update the Mail Stop and phone number listed to Mail Stop TWB-05 B32M and 1-630-829-9565.

Response: Paragraph c.1. will be revised to reflect the change in Mail Stop and phone number as well as the zip code and the use of "https" instead of "http."

Comment: Unclear language exists in RH-3002.d.1., "Purpose and Scope."

Response: The language will be simplified so that readers will be more clearly directed to Part C of Section 4 that contains the exemption requirements.

Comment: For consistency and simplicity, “this Section” should be used in RH-3305.a. and RH-3306.a.

Response: “This Section,” instead of the Section number and its title, will be used.

Comment: A type-o exists where paragraph c. of RH-3508. is incorrectly shown as paragraph d.

Response: Paragraph c. will be shown as such.

Michael Harry, attorney for the Bureau of Legislative Research, asked the Department of Health regarding the authority of the Center for Health Protection to promulgate this rule as the statutes confer the authority to the State Radiation Control Agency.

Robert Brech, Department of Health, responded that the Department of Health placed the State Radiation Control Agency under the division of the Center for Health Protection for organizational purposes.

The proposed effective date is September 1, 2017.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Department of Health has general authority to make all necessary and reasonable rules and regulations for the protection of the public health and safety. Arkansas Code Annotated §20-7-109(a) (1) (A). The current rule is promulgated under Ark. Code Ann. §20-21-207(3) which authorizes the State Radiation Control Agency (under the authority of the Department of Health) to “[f]ormulate, adopt, promulgate, and repeal codes, rules, and regulations which may provide for licensing or registration relating to control, storage, or disposal of sources of ionizing radiation with due regard for compatibility with the regulatory programs of the federal government...”