ARKANSAS REGISTER



Proposed Rule Cover Sheet

Secretary of State John Thurston 500 Woodlane, Suite 026 Little Rock, Arkansas 72201-1094 (501) 682-5070 www.sos.arkansas.gov



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| Agency or Division Name | | | | |
| Other Subdivision or Department, If Applicable | | | | |
| Previous Agency Name, If Applicable | | | | |
| Contact Person_ | | | | |
| Contact E-mail | | | | |
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| Name of Rule | | | | |
| Newspaper Name | | | | |
| Date of Publishing | | | | |
| Final Date for Public Comment | | | | |
| Location and Time of Public Meeting | | | | |

NOTICE OF PUBLIC COMMENT PERIOD

The Arkansas Department of Health is holding a public comment period to allow interested persons to comment on the proposed adoption of revisions to the Arkansas State Board of Health Rules for Control of Sources of Ionizing Radiation pursuant to the Administrative Procedures Act as amended, Ark. Code Ann. 25-15-201 et seq., by the authority of Ark. Code Ann. 20-21-201-222.

The proposed revisions are available for inspection online through the ADH website at www.healthy.arkansas.gov, "Rules" link. Copies may be obtained by calling the Radiation Control Section at (501) 661-2301. The proposed revisions will also be available for public inspection and copying at the Arkansas Department of Health, Radiation Control Section, Freeway Medical Tower, 5800 West 10th Street, Suite 401.

The public may submit written comments to <u>adh.ram@arkansas.gov</u>, in person at 5800 West 10th Street – Suite 401, or to the Radiation Control Section Chief, Radiation Control Section, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas, 72205-3867, no later than 10:00 a.m. on September 30, 2021.

ARKANSAS STATE BOARD OF HEALTH

Radiation Control Programs

RULES AND REGULATIONS FOR CONTROL OF SOURCES OF IONIZING RADIATION

Promulgated Under the Authority of Act 96 of 1913 and Act 8 of the Second Extraordinary Session of 1961, As Amended

This Revision Effective October 1, 2017 December 1, 2021

By the Arkansas State Board of Health

Arkansas Department of Health Little Rock, Arkansas

Nathaniel Smith, MD, MPH

José R. Romero, MD

Director

Secretary of Health

SECTION 1. REGISTRATION OF SOURCES OF RADIATION

PART B. DEFINITIONS

RH-10. **Definitions**.

Person -

- Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, or any other state or political subdivision or agency thereof; and
- any Any legal successor, representative, agent, or agency of the foregoing, other than the but not including United States Nuclear Regulatory Commission and other federal government Government agencies.

Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

PART C. REGISTRATION OF RADIATION MACHINES

RH-21. **Initial Registration**.

f. An application for registration will be approved if the Department
determines that an application meets the requirements of the Act and these
Rules. The registration authorizes the proposed activity in such form and
containing such conditions and limitations as the Department deems
appropriate or necessary to effectuate the purposes of the Act.

RH-23. <u>Radiation Machine Registration Forms.</u>

<u>Initial Rregistration</u> and <u>renewal subsequent notifications to the Department shall</u> be made on forms <u>furnished by the Department RC FORM 200 and RC FORM 201</u>, as applicable, The registration or renewal of registration and shall set forth <u>contain</u> all <u>applicable appropriate</u> information <u>ealled for required</u> by the forms. The Department may request additional information as part of the registration process.

RH-25. Special Registration.

If the reporting of each installation or other information called for is impractical, the Department, upon the request of a registrant, may approve registration in such special form as the Department may prescribe.

Terms and Conditions of Registrations.

- a. Each registration issued pursuant to this Section shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules and orders of the Department.
- b. No registration issued under this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any registration to any person unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.
- c. Each person registered by the Department pursuant to this Section shall confine use and possession of the radiation machine registered to the locations and purposes authorized in the registration.
- d. The Department may incorporate in the registration at the time of issuance, or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the registrant's possession, use, and transfer of radiation machines subject to this Section as it deems appropriate or necessary in order to:
 - 1. Protect health or to minimize danger to life or property;
 - Require such reports and the keeping of such records as may be necessary or appropriate to effectuate the purposes of the Act; and
 - 3. Prevent loss or theft of radiation machines subject to this Section.
- e. The Department may request, and the registrant shall provide, additional information after the registration has been issued to enable the Department to determine whether the registration should be modified in accordance with RH-29.

RH-26. **Report of Changes**.

The registrant shall notify the Department in writing of any changes that would render the information contained in the application for registration no longer accurate, including, but not limited to, the following changes: name or mailing address of the registrant; location of the installation or an additional use location; designation of the Radiation Safety Officer; and the receipt, sale, or disposal of any reportable source of radiation machine; and placement or removal of a radiation machine into or out of storage. Notification of the Department is required within ten (10) days of a change, unless the change involves a machine use listed in RH-21.b. Changes regarding RH-21.b. uses must be reported in writing to the Department prior to the change being made.

RH-27. **Report of Discontinuance**.

Every registrant who permanently discontinues the use of, or permanently disposes of, all his reportable sources of radiation machines at an installation shall notify the Department in writing within ten (10) days of such action. The notice shall be signed by the registrant or other individual duly authorized to act for and on his behalf.

RH-28. Deleted.

Report of Termination.

Every registrant who permanently disposes or transfers all his radiation machines at an installation shall, within ten (10) days of such action:

- 1. Notify the Department in writing, signed by the registrant or other individual duly authorized to act for and on his behalf; and
- 2. Submit to the Department a record of the disposal of the radiation machines, if applicable; and if transferred, to whom they were transferred.

RH-29. Reserved.

Modification, Suspension, and Revocation of Part C Registrations.

a. The terms and conditions of registrations issued pursuant to Part C of this

Section shall be subject to revision or modification. A registration may be

suspended or revoked by reason of amendments to the Act or by reason of
rules or orders issued by the Department.

- b. Any registration may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act or of these Rules, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a registration on an original application, or for violation of, or failure to observe any of, the terms and conditions of the Act, or the registration, or of any rule or order of the Department.
- c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing, and the registrant shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.
- d. Each registration revoked by the Department expires with the

 Department's final determination to revoke the registration, or on the
 expiration date stated in the determination, or as otherwise provided by
 Department Order.

PART D. REGISTRATION OF VENDOR SERVICES

RH-32. **Vendor Services Registration Forms**.

Registration and renewal changes to a registration shall be completed made on forms furnished by the Department RC FORM 800 or RC FORM 801, as applicable, and shall contain all information required by the Department as indicated on the forms and accompanying instructions. The Department may request additional information as part of the registration process.

RH-36. Modification, Suspension, and Revocation of Part D Registrations.

- a. The terms and conditions of registrations issued pursuant to Part D of this Section shall be subject to revision or modification. A registration may be suspended or revoked by reason of amendments to the Act, or by reason of rules or orders issued by the Department.
- b. Any registration may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act or of these Rules, or because of conditions revealed by such application or statement of fact or any report,

record, or inspection or other means which would warrant the Department to refuse to grant a registration on an original application, or for violation of, or failure to observe any of, the terms and conditions of the Act, or the registration, or of any rule or order of the Department.

- c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing, and the registrant shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.
- d. Each registration revoked by the Department expires with the

 Department's final determination to revoke the registration, or on the
 expiration date stated in the determination, or as otherwise provided by
 Department Order.

SECTION 2. LICENSING OF RADIOACTIVE MATERIALS

PART B. DEFINITIONS

RH-200. **Definitions**.

Authorized nuclear pharmacist - A pharmacist who:

- 1. Meets the requirements in RH-8317.; or
- 2. Is identified as an authorized nuclear pharmacist on a specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Department, U.S. Nuclear Regulatory Commission, or Agreement State; or
- 3. Is identified as an authorized nuclear pharmacist on a permit issued by a Department, U.S. Nuclear Regulatory Commission, or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material.

Authorized user - A physician, dentist, or podiatrist who:

- 1. Meets the requirements in RH-8318. and RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8610., RH-8615., RH-8621., or RH-8660.; or
- 2. Is identified as an authorized user on a license or equivalent permit issued by the Department, U.S. Nuclear Regulatory Commission, or Agreement State; or
- 3. Is identified as an authorized user on a permit issued by a Department, U.S. Nuclear Regulatory Commission, or Agreement State specific license of broad scope that is authorized to permit the medical use of radioactive material.

Person -

- 1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the U.S. Nuclear Regulatory Commission or the U.S. Department of Energy (except that the DOE shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the NRC under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and
- 2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

Physician - Any individual possessing a valid physician's and surgeon's certificate issued by this state A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

PART D. LICENSES

RH-409. Specific Terms and Conditions of Licenses.

- a. Each license issued pursuant to these Regulations Rules shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Department.
- b. 1. No license issued or granted pursuant to these Regulations Rules nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.
 - 2. An application for transfer of license must include:
 - A. The identity, technical, and financial qualifications of the proposed transferee; and
 - B. Financial assurance for decommissioning information required by RH-409.h.
- c. Each person licensed by the Department pursuant to these Regulations
 Rules shall confine his use and possession and use of the material licensed material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to these Regulations Rules shall carry with it the right to receive, acquire, receive title to, own, possess, and use radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Section 4 of these Regulations Rules.
- d. The Department may incorporate, in any license issued pursuant to these Regulations Rules, at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material as it deems appropriate or necessary in order to:
 - 1. Protect health or to minimize danger to life or property;
 - 2. Require such reports and the keeping of such records and to provide for such inspections of activities under the license as may

be necessary or appropriate to effectuate the purposes of the Act and these Regulations rules thereunder-; and

3. Prevent loss or theft of licensed material.

RH-409. (Cont'd)

- e. Each licensee shall notify the Department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license. This notification requirement applies to all specific licenses issued under these Regulations Rules.
- f. Licensees required to submit emergency plans by RH-403.g. shall follow the emergency plan approved by the Department. Proposed changes to the plan may not be implemented without prior application to and prior approval by the Department.
- g. Bankruptcy notification.
 - 1. Each general licensee that is required to register by RH-402.c.13. and each specific licensee shall notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:
 - A. The licensee;
 - B. An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the licensee as property of the estate; or
 - C. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.
 - 2. This notification must indicate:
 - A. The bankruptcy <u>C</u>court in which the petition for <u>B</u>bankruptcy was filed; and,
 - B. The case name and number; and
 - **B** C. The date of the filing of the petition.

SECTION 3. STANDARDS FOR PROTECTION AGAINST RADIATION

PART B. DEFINITIONS

RH-1100. **Definitions**.

Person -

- 1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the U.S. Nuclear Regulatory Commission or the U.S. Department of Energy (except that the DOE shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the NRC under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and
- 2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

PART I. LICENSES FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

RH-1801. Equipment Control.

k. **Notifications**.

3. Any licensee or registrant conducting radiographic operations or storing radioactive material at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, shall notify the Department prior to exceeding the 180 days.

SECTION 4. TRANSPORTATION OF RADIOACTIVE MATERIALS

PART F. OPERATING CONTROLS AND PROCEDURES

RH-3509. Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste.

- a. 1. As specified in paragraphs b., c., and d. of this section, each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.
 - 2. As specified in paragraphs b., c., and d. of this section, after June 11, 2013, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph c.3.C of this section, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.
- b. Advance notification is also required under this section for the shipment of licensed material, other than irradiated fuel, meeting the following three conditions:
 - 1. The licensed material is required by this Section to be in Type B packaging for transportation;
 - 2. The licensed material is being transported to or across a State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and
 - 3. The quantity of licensed material in a single package exceeds the least of the following:

- A. 3000 times the A₁ value of the radionuclides as specified in Table A-1 of Appendix A to Section 4 for special form radioactive material;
- B. 3000 times the A₂ value of the radionuclides as specified in Table A-1 of Appendix A to Section 4 for normal form radioactive material; or
- C. 1000 TBq (27,000 Ci).
- c. Procedures for submitting advance notification.
 - 1. The notification must be made in writing to:
 - A. The office of each appropriate governor or governor's designee;
 - B. The office of each appropriate Tribal official or Tribal official's designee; and
 - C. The Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.
 - 2. A notification delivered by mail must be postmarked at least seven (7) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.

RH-3509.c. (Cont'd)

- 3. A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least four (4) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.
 - A. A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306). Reserved.
 - B. Contact information for each State, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing

addresses of Tribal officials and Tribal officials' designees, is available on the U.S. Nuclear Regulatory Commission website at https://scp.nrc.gov/special/designee.pdf.

- C. A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
- 4. The licensee shall retain a copy of the notification as a record for three (3) years.
- d. Information to be furnished in advance notification of shipment.

Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

- 1. The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;
- 2. A description of the irradiated reactor fuel or nuclear waste shipment, as specified in the regulations of DOT the U.S. <u>Department of Transportation</u> in 49 CFR 172.202 and 172.203(d);
- 3. The point of origin of the shipment and the seven (7) day period during which departure of the shipment is estimated to occur;

RH-3509.d. (Cont'd)

- 4. The seven (7) day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;
- 5. The destination of the shipment, and the seven (7) day period during which arrival of the shipment is estimated to occur; and
- 6. A point of contact, with a telephone number, for current shipment information.

e. Revision notice.

A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three (3) years.

f. Cancellation notice.

- 1. Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and the Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.
- 2. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three (3) years.

SECTION 5. RULES OF PRACTICE

PART B. ADMINISTRATION

RH-4005. Administrative Examination of Applications.

Applications for the issuance of a license <u>or registration</u>, amendment of a license <u>or registration</u> at the request of the holder, and renewal of a license <u>or registration</u> will be given a docket <u>number</u> or other <u>identifying number identifier</u> for administrative examination. The applicant may be required to submit additional information and may be requested to confer informally regarding the application. The Department will give to others such notice of the filing of applications as is required under the applicable provisions of these <u>Regulations Rules</u> and such additional notices as it deems appropriate.

RH-4006. Action on Application, Hearings.

a. The Department will, upon request of the applicant or intervener and may upon its own initiative, direct the holding of a formal hearing prior to taking action on the application. If no prior formal hearing has been held and no notice of proposed action has been served as provided in paragraph booth of this section, the Department will direct the holding of a formal hearing upon receipt of a request therefore from the applicant or intervener within thirty (30) days after the issuance of a license or registration or other approval or a notice of denial.

RH-4008. **Notice of Violation**.

Prior to the institution of any proceeding for the modification, suspension, a. or revocation of a license or registration for alleged violation of any provision of the Act, these Regulations Rules, or conditions of a license, or a registration, the licensee or registrant shall be served with a written notice calling the facts to his/her attention and requesting a written explanation or statement in reply. Within fifteen (15) thirty (30) days of the receipt date of such the notice or other specified time, the licensee or registrant shall send his/her reply to the Department. If the notice relates to conditions or conduct which that may be susceptible to correction or to being brought into full compliance by action of the licensee or registrant, he/she shall state in his/her reply the corrective steps that have been taken and the results achieved, or to be instituted in achieving correction and preventing further violations the corrective steps that will be taken, and the date when such correction and full compliance will be achieved. Corrective actions must address methods to prevent future noncompliance.

RH-4009. Orders.

In any case described in RH-4008. of this Regulation, the Department may issue to the licensee or registrant a notice to comply with the applicable provisions of the Act or the rules and regulations of the Arkansas State Board of Health or any order issued by the Department. The order shall apprise the licensee or registrant that he/she has the right to request a hearing within thirty (30) days by making a written request therefore to the Director. In the event a request for a hearing is received by the Director within the time specified, a notice of hearing shall be issued by the Department in accordance with RH-4028. of these Regulations.

RH-4029. Answer.

a. Within the time allowed by the notice of hearing for filing and serving an answer, and as required, the answer of a licensee, registrant, or applicant

shall fully advise the Department and any other parties as to the nature of the defense or other position of the answering party, the issues he/she proposes to controvert and those he/she does not controvert, and whether or not he/she proposes to appear and present evidence. If facts are alleged, the answer shall admit or deny specifically each allegation of fact; or where knowledge is lacking, the answer may so state and the statement shall operate as a denial. Allegations of fact not denied shall be deemed to be admitted. Matters alleged as affirmative defenses or positions shall be separately stated and identified and, in the absence of a reply, shall be deemed to be controverted. The answer of an intervener shall fully advise the Department and other parties of his/her position and whether or not he/she proposes to appear and present evidence.

SECTION 6. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

PART B. DEFINITIONS

RH-5100. **Definitions.**

Person -

- 1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this State state, any other State state or political subdivision or agency thereof; and
- 2. any Any legal successor, representative, agent, or agency of the foregoing, other than the but not including U.S. Nuclear Regulatory Commission and other federal United States government Government agencies.

SECTION 8. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

PART E. RECORDS AND REPORTS

RH-7083. Reports.

- a. In addition to the reporting requirements in other Sections of these Regulations Rules, the licensee shall report the following events if not reported under other Sections of the Department Regulations rules: ...
- b. The report must include a telephone report within 24 (twenty-four) hours as described in RH-1502.g.1.601.c.1. and a written report within thirty (30) days as described in RH-1502.g.2601.c.2.

SECTION 9. USE OF RADIONUCLIDES IN THE HEALING ARTS

PART B. DEFINITIONS

RH- 8100. **Definitions**.

Authorized nuclear pharmacist means a pharmacist who:

- 1. Meets the requirements in RH-8317.a. and RH-8319.; or
- 2. Is identified as an authorized nuclear pharmacist on:
 - A. A specific license issued by the Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;
 - B. A permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;
 - C. A permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

- D. A permit issued by a Nuclear Regulatory Commission master material license broad scope medical use committee permittee that authorizes medical use or the practice of nuclear pharmacy; or
- 3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
- 4. Is designated as an authorized nuclear pharmacist in accordance with RH-405.1.2.D.

Authorized user means a physician, dentist, or podiatrist who:

- 1. Meets the requirements in RH-8319. and RH-8510.a., RH-8540.a., RH-8560.a., RH-8570.a., RH-8580.a., RH-8610.a., RH-8615.a., RH-8621.a., or RH-8660.a.; or
- 2. Is identified as an authorized user on:
 - A. A Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material:
 - B. A permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;
 - C. A permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or
 - D. A permit issued by a Nuclear Regulatory Commission master material license broad scope committee permittee that is authorized to permit the medical use of radioactive material.

Physician (as used in this Section) – A doctor of medicine or doctor of osteopathy licensed by the appropriate authority Arkansas State Medical Board to prescribe drugs in the practice of medicine in the state in which the Department is located.

SECTION 11. THERAPEUTIC RADIATION MACHINES

PART B. DEFINITIONS

RH-10100. **Definitions**.

Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

SECTION 12. PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

PART A. GENERAL

RH-11005. **Definitions**.

Person -

- Any individual, corporation, partnership, firm, association, trust, estate, 1. public or private institution, group, Government agency other than the U.S. Nuclear Regulatory Commission or the U.S. Department of Energy (except that the DOE shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the NRC under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and
- 2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

PART B. BACKGROUND INVESTIGATIONS AND ACCESS AUTHORIZATION PROGRAM

RH-11023. Access Authorization Program Requirements.

- b. Reviewing officials.
 - 1. Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.
 - 2. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the Department by an appropriate method listed in RH-11007. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten (10) years in accordance with RH-11025.c.

RH-11027. Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material.

- c. Procedures for processing of fingerprint checks.
 - 1. For the purpose of complying with this Part, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security Physical and Cyber Security Policy, 11545 Rockville Pike, Rockville, Maryland 20852, ATTN: Criminal History Program, Mail Stop TWB 05 B32M T-07D04M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555 0001, by calling 1-630-829-9565, or by email to FORMS.Resource@nrc.gov emailing

<u>MAILSVS.Resource@nrc.gov</u>. Guidance on submitting electronic fingerprints can be found at https://www.nrc.gov/site-help/e-submittals.html https://www.nrc.gov/security/chp.html.

RH-11027.c. (Cont'd)

- 2. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security Division of Physical and Cyber Security Policy at 1-301-492-3531 by emailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The U.S. Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the Electronic Submittals Licensee Criminal History Records Checks & Firearms Background Check Information page at https://www.nrc.gov/site-help/esubmittals.html https://www.nrc.gov/security/chp.html and see the link for the Criminal History Program under Electronic Submission Systems. "How do I determine how much to pay for the request?")
- 3. The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

PART C. PHYSICAL PROTECTION REQUIREMENTS DURING USE

RH-11043. General Security Program Requirements.

- d. **Protection of information**.
 - 1. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.
 - 2. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan,

and implementing procedures, and the list of individuals that have been approved for unescorted access.

- 3. Before granting an individual access to the security plan, or implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:
 - A. Evaluate an individual's need to know the security plan, or implementing procedures, or the list of individuals that have been approved for unescorted access; and

RH-11043.d.3. (Cont'd)

- B. If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in RH-11025.a.2. through a.7.
- 4. Licensees need not subject the following individuals to the background investigation elements for protection of information:
 - A. The categories of individuals listed in RH-11029.a.; or
 - B. Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in RH-11025.a.2. through a.7., has been provided by the security service provider.
- 5. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, or implementing procedures, or the list of individuals that have been approved for unescorted access.
- 6. Licensees shall maintain a list of persons currently approved for access to the security plan, or implementing procedures, or the list of individuals that have been approved for unescorted access.

 When a licensee determines that a person no longer needs access to

the security plan, or implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven (7) working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, or implementing procedures, or the list of individuals that have been approved for unescorted access.

7. When not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

RH-11043.d. (Cont'd)

- 8. The licensee shall retain as a record for three (3) years after the document is no longer needed:
 - A. A copy of the information protection procedures; and
 - B. The list of individuals approved for access to the security plan, or implementing procedures, or the list of individuals that have been approved for unescorted access.

RH-11045. LLEA Coordination.

- b. The licensee shall notify the Department as specified in RH-11007. within three (3) business days if:
 - 1. The LLEA has not responded to the request for coordination within sixty (60) days of the coordination request; or
 - 2. The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

PART D. PHYSICAL PROTECTION IN TRANSIT

RH-11077. Advance Notification of Shipment of Category 1 Quantities of Radioactive Material.

As specified in paragraphs a. and b. of this section, each licensee shall provide advance notification to the Department and to the governor of a State, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the State, before the transport, or delivery to a carrier for transport, of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. Procedures for submitting advance notification.

- 1. The notification must be made to the Department and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of the Department and of governors and governors' designees, is available on the U.S. Nuclear Regulatory Commission website at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 0001

 Department. The notification to the Department may be made by fax to 1-501-280-4407 email to Communication.Center@arkansas.gov.
- 2. A notification delivered by mail must be postmarked at least seven (7) days before transport of the shipment commences at the shipping facility.

RH-11077.a. (Cont'd)

3. A notification delivered by any means other than mail must reach the Department at least four (4) days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least four (4) days before transport of a shipment within or through the State.

b. Information to be furnished in advance notification of shipment.

Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

- 2. The license numbers of the shipper and receiver;
- 3. A description of the radioactive material contained in the shipment, including the radionuclides and quantity;
- 4. The point of origin of the shipment and the estimated time and date that shipment will commence;
- 5. The estimated time and date that the shipment is expected to enter each State along the route;
- 6. The estimated time and date of arrival of the shipment at the destination; and
- 7. A point of contact, with a telephone number, for current shipment information.

c. Revision notice.

1. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the State or the governor's designee and to the Department.

RH-11077.c. (Cont'd)

2. A licensee shall promptly notify the governor of the State or the governor's designee of any changes to the information provided in accordance with paragraphs b. and c.1. of this section. The licensee shall also immediately notify the Department of any such changes.

d. Cancellation notice.

Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified and to the Department. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

e. Records.

The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three (3) years.

f. Protection of information.

State officials, State employees, and other individuals, whether or not licensees of the Department, the NRC, or of an Agreement State, who receive schedule information of the kind specified in RH-11077.b. shall protect that information against unauthorized disclosure as specified in RH-11043.d.

RH-11081. Reporting of Events.

- g. The initial telephone notification required by paragraphs a. through d. of this section must be followed within a period of thirty (30) days by a written report submitted to the Department by an appropriate method listed in RH-11007. A written report is not required for notifications on suspicious activities required by paragraphs c. and d. of this section. The report must set forth the following information, as appropriate:
 - 1. A description of the licensed material involved, including kind, quantity, and chemical and physical form;
 - 2. A description of the circumstances under which the loss, theft, etc. occurred;
 - 3. A statement of disposition, or probable disposition, of the licensed material involved;
 - 4. Actions that have been taken, or will be taken, to recover the material; and
 - 5. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of this type of event.

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

| DE | CPARTMENT/AGENCY | | | | | |
|-----|--|--|--|--|--|--|
| | VISION | | | | | |
| DI | VISION DIRECTOR | | | | | |
| CC | ONTACT PERSON | | | | | |
| AΓ | DDRESS | | | | | |
| PH | IONE NO FAX NO E-MAIL | | | | | |
| NA | DDRESSE-MAILE-MAILE-MAILE-MAIL | | | | | |
| PR | ESENTER E-MAIL | | | | | |
| | INSTRUCTIONS | | | | | |
| Α. | Please make copies of this form for future use. | | | | | |
| В. | 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 D. Rule" below. | | | | | |
| Е. | Submit two (2) copies of the Questionnaire and Financial Impact Statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to: | | | | | |
| | Jessica C. Sutton | | | | | |
| | Administrative Rules Review Section | | | | | |
| | Arkansas Legislative Council | | | | | |
| | Bureau of Legislative Research One Capitol Mall, 5th Floor | | | | | |
| | Little Rock, AR 72201 | | | | | |
| *** | | | | | | |
| 1. | What is the short title of this rule? | | | | | |
| 2. | What is the subject of the proposed rule? | | | | | |
| 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. | | | | | |
| | | | | | | |
| 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 | | | | | |

| Does this repeal an existing rule? Yes No If yes, a copy of the repealed rule is to be included wit completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule 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. | |
| 7. | What is the purpose of this proposed rule? Why is it necessary? | |
| | | |
| | | |

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

| 8. | by Arkansas Code § 25-19-108(b). | | | | |
|---|--|--|--|--|--|
| 9. | Will a public hearing be held on this proposed rule? Yes No If yes, please complete the following: | | | | |
| | Date: | | | | |
| | Time: | | | | |
| | Place: | | | | |
| 10. When does the public comment period expire for permanent promulgation? (Must provide a date.) | | | | | |
| 11. | 11. What is the proposed effective date of this proposed rule? (Must provide a date.) | | | | |
| 12. | Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice | | | | |
| 13. | Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e). | | | | |
| 14. | 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. | | | | |
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FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

| DI | EPARTMENT |
|----|---|
| DI | IVISION |
| PE | ERSON COMPLETING THIS STATEMENTELEPHONE NOFAX NOEMAIL: |
| Γŀ | ELEPHONE NO FAX NO EMAIL: |
| | o comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file to (2) copies with the Questionnaire and proposed rules. |
| SH | HORT 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 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; |
| | |
| | |
| | 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 fed <u>Current Fiscal Year</u> | eral rule or regulation? <u>Next Fiscal Year</u> | | |
| | General Revenue Federal Funds Cash Funds | Federal Funds | | |
| | Cash Funds Special Revenue Other (Identify) | Cash Funds Special Revenue Other (Identify) | | |
| | Total | Total | | |
| | b) What is the additional cost of the state rule? | | | |
| | Current Fiscal Year | Next Fiscal Year | | |
| | General Revenue Federal Funds Cash Funds | General Revenue Federal Funds Cash Funds | | |
| | Special Revenue Other (Identify) | Special Revenue Other (Identify) | | |
| | Total | Total | | |
| 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 | | |
| | \$ | \$ | | |
| 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 | | |
| | \$ | \$ | | |
| | | | | |

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.

PROPOSED REVISIONS TO THE ASBH RULES FOR CONTROL OF SOURCES OF IONIZING RADIATION

JULY 2021 RULE PACKAGE

The Radiation Control Section is initiating the process for the revision of the Arkansas State Board of Health Rules 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 rules are driven by our agreement with the U.S. Nuclear Regulatory Commission (NRC). The State of Arkansas, as an Agreement State, must have rules that are compatible with NRC regulations. The following revisions are being proposed.

• Revisions concerning NRC regulation amendments:

Miscellaneous Corrections Amendments (3) – 10 CFR Parts 1, 2, 21, 34, 37, 40, 50, 52, 70, 71, 73, 110, and 140:

The objective of these three rules is to make miscellaneous corrections concerning office, division, and agency references and functions; remove a follow up reporting instruction; correct cross reference, typographical, and grammatical errors; add a certification recipient and clarifying language; remove obsolete language; and correct mailing, email, and web page addresses. (Sections 2, 3, 4, and 12)

• Revisions due to Act 268 of 2021:

Changes include those provisions presented in Section 1 (Registration of Sources of Radiation), definitions of "person" and "physician," and provisions presented in Section 5 (Rules of Practice).

Revisions not in conjunction with a particular NRC regulation amendment (general clean up):

Changes include deletion or revision of two radioactive material healing arts definitions, correction of references found in RH-7083.b., and addition of form numbers to RH-23.