

## DEPARTMENT OF HEALTH

### SUBJECT: Control of Sources of Ionizing Radiation

**DESCRIPTION:** The Radiation Control Section has initiated 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 (as well as some general clean-up) are being addressed, as listed below:

- **Decommissioning Planning** – to improve decommissioning planning and thereby reduce the likelihood that any current operating facility will become a legacy site; to require licensees to conduct their operations to minimize the introduction of residual radioactivity into the site, which includes the site’s subsurface soil and groundwater; to require licensees to report additional details in their decommissioning cost estimate, eliminate the escrow account and line of credit as approved financial assurance mechanisms, and modify other financial assurance requirements (*Sections 2 and 3*)
- **Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste** – to require licensees to provide advance notification to participating Federally-recognized Tribal governments regarding shipments of irradiated reactor fuel and certain nuclear wastes for any shipment that passes within or across their reservations (*Section 4*)
- **Technical Corrections** – to make technical corrections in certain parts of the regulations, including typographical and spelling errors, and other edits and conforming changes (*Sections 2, 3, and 4*)
- **Requirements for Distribution of Byproduct Material** – to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date; to redefine categories of devices to be used under exemptions, adding explicit provisions regarding the sealed source and device registration process, and adding flexibility to the licensing of users of sealed sources and devices (*Section 2*)

Also, the following sections not in conjunction with a particular NRC regulation amendment have been revised in order to reflect compatibility with the NRC as well:

- Posting of panoramic and underwater irradiators (*RH-7023.g.*)
- Exemption of common and contract carriers from the regulations (*RH-302.*) - *RH-402.j.* to be deleted which currently indicates general licensing Exempt Quantity and Exempt Concentration tables (*Schedules B and C to S*)

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**PUBLIC COMMENT:** A public hearing was held on this rule on December 9, 2014. The public comment period expired December 9, 2014. The Department received the following public comment:

## **U.S. Nuclear Regulatory Commission**

**COMMENT:** RH-402.j.3.E. contains a reference to 10 CFR 30.6(a). This reference should be revised to list the appropriate method of communication with the Department.

**RESPONSE:** The phrase “by an appropriate method listed in 10 CFR 30.6(a)” will be removed from the proposed RH-402.j.3.E. (currently RH-405.q.3.E.).

The proposed effective date for the final rule is August 6, 2015.

**CONTROVERSY:** This is not expected to be controversial.

**FINANCIAL IMPACT:** Large sealed source user financial assurance for decommissioning would increase from \$113,000 to approximately \$1,000,000, dependent upon a submitted, detailed cost estimate that is site-specific. Sealed source financial assurance revisions would affect one licensee. The financial instrument chosen determines the actual cost incurred by the licensee.

There is no cost to the state, county, or municipal government to implement the rule.

The Radiation Control Section offers the following written findings in conjunction with the Financial Impact Statement:

- 1) Revisions to RH-409.h., “Financial assurance and recordkeeping for decommissioning,” are being proposed in order to have comparable financial assurance requirements as found in other Agreement States and in States regulated by the U.S. Nuclear Regulatory Commission. A financial assurance arrangement for decommissioning of a facility or site is necessary should a licensee possessing large amounts of radioactive material suddenly go defunct. These regulation revisions would require those licensed for large amounts of sealed radioactive sources to provide a site-specific, detailed cost estimate via a decommissioning funding plan. Financial assurance for decommissioning is provided by way of an approved financial instrument. The decommissioning funding plan requirement for sealed source users would currently affect one licensee in the State.
- 2) Under the current regulations, provisions for financial assurance regarding this type of licensee are grossly inadequate. Should a licensee go defunct, as described above, the State might then have to bear the costs of decommissioning in order to decrease the likelihood of contamination and/or exposure of members of the public. Acceptable financial assurance requirements must be adopted by an Agreement State at the Health and Safety designation level in order to maintain “adequacy” in the Agreement State program. In 2003, the U.S. Nuclear Regulatory Commission amended its financial assurance regulations to incorporate the requirement of a decommissioning funding plan for this type of licensee.

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3) Under the current regulations, these particular sealed source users (RH-409.h.1.B.) have the ability to either submit a certification that financial assurance for decommissioning has been provided in an amount prescribed in RH-409.h.4. (\$113,000) or submit a decommissioning funding plan that contains a cost estimate for decommissioning. The proposed rule eliminates the ability of this type of licensee to provide the \$113,000 amount that has now been deemed inadequate due to inflation and an increase in source disposal costs. A survey was taken of Agreement State and U.S. Nuclear Regulatory Commission licensees that supports this opinion. Based on the survey, cost estimates ranging from \$354,000 – \$1,790,000 were determined in regards to licensees similar to the one that would be affected in our State. Variability exists due to site-specific conditions such as accessibility, the quantity of radioactive material present on-site to be disposed, transportation costs, etc. The financial instrument chosen by the licensee to meet financial assurance requirements determines the actual cost incurred by the licensee.

Having funds available for decommissioning ensures the protection of public health and safety, decontamination and decommissioning of the facility or site, and allows for disposal of radioactive materials in the event of abandonment, insolvency, or other inability of the licensee to meet the requirements.

4) Any less costly alternative would not address the full site-specific, detailed cost estimate derived in order to be able to release the facility.

5) No alternatives to the proposed rule have been suggested as a result of public comment.

6) This is an amendment to an existing rule.

7) RH-409.h.1.B. regarding the requirement of financial assurance in the form of a decommissioning funding plan for those licensees licensed for large amounts of sealed radioactive sources will be reviewed at least every ten years to determine, based upon the evidence, whether there remains a need for the rule.

**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,

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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, 5<sup>th</sup> Floor  
Little Rock, AR 72201

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

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.

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. 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.

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: December 9, 2014

Time: 10:00 a.m.

Place: 5800 West 10<sup>th</sup> Street, Room 906,  
Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)  
December 9, 2014

11. What is the proposed effective date of this proposed rule? (Must provide a date.)  
February 15, 2015

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.

radioactive material licensees

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**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?

<u>Current Fiscal Year</u>	<u>Next Fiscal Year</u>
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

Large sealed source user financial assurance for decommissioning would increase from \$113,000 to approximately \$1,000,000, dependent upon a submitted, detailed cost estimate that is site-specific. Sealed source financial assurance revisions would affect one licensee. The financial instrument chosen determines the actual cost incurred by the licensee.

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.