

#### DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

**SUBJECT:** Rules for Control of Sources of Ionizing Radiation

**<u>DESCRIPTION</u>**: 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 for numbers to RH-23.

<u>PUBLIC COMMENT</u>: No public hearing was held on this proposed rule. The public comment period expired on September 30, 2021. The agency provided the following summary of the single public comment it received and its response to that comment.

Commenter's Name: Dr. James Raker

**COMMENT:** The term "physician" in AR legally means MD, DO, and DC. Make sure that legal definition is used in your Rule definition of a "physician."

RESPONSE: The definition of "physician" in the Rules for Control of Sources of Ionizing Radiation is taken verbatim from the Arkansas Code at A.C.A. § 20-21-203 (26) which is the area of AR Code setting forth State policy and requirements for Rules concerning Ionizing Radiation Sources, such as Nuclear Materials. This portion of AR law also reflects the requirements of the US Nuclear Regulatory Commission. These Rules govern the requirements for radioactive material for diagnostic or therapeutic purposes - for example, radiation therapy for a cancer patient. These Rules are not applicable to, or affect, Chiropractors and their use of x-ray machines in their practice. Chiropractors are governed by and listed with other Practitioners in a separate area of the AR Code known as the "Consumer-Patient Radiation Health and Safety Act" at A.C.A. § 17-106-103(5). The definition in our Rules and the AR Code for Ionizing Radiation Sources does not modify or change the broader definition of Physician found in the AR Chiropractic Practices Act at A.C.A. § 17-81-101 et seq.

The proposed effective date is December 1, 2021.

**<u>FINANCIAL IMPACT</u>**: The agency indicated that this proposed rule does not have a financial impact.

**LEGAL AUTHORIZATION:** "The State Board of Health is designated as the State Radiation Control Agency." Ark. Code Ann. § 20-21-206(a). As such, the Board "shall provide by rule for licensing of radioactive material, or devices or equipment utilizing such material, and for licensing or registration of radiation equipment." Ark. Code Ann. § 20-21-213(a). Portions of this rule implement Act 268 of 2021, sponsored by Representative Jack Ladyman. The Act amended and updated the Arkansas Code regarding regulation of ionizing radiation to comply with federal laws and regulations.



## Arkansas Department of Health

4815 West Markham Street ◆ Little Rock, Arkansas 72205-3867 ◆ Telephone (501) 661-2000 Governor Asa Hutchinson José R. Romero, MD, Secretary of Health

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

August 9, 2021

#### **PURPOSE**

The Arkansas Department of Health (Department) is seeking Governor Hutchinson's review of proposed amendments to the Rules for Control of Sources of Ionizing Radiation.

#### **BACKGROUND**

Pursuant to A.C.A. §§ 20-21-203—217 the Department has authority to promulgate rules for the Control of Sources of Ionizing Radiation. These rules are reviewed and updated in conjunction with the United States Nuclear Regulatory Commission to ensure it agrees with Federal Regulations.

#### **KEY POINTS**

The proposed rule:

- o Makes miscellaneous corrections to references and descriptions
- o Removes obsolete language
- o Makes revisions due to Act 268 of 2021

#### **DISCUSSION**

The Radiation Control Section of the Department 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 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 rules that are compatible with NRC regulations. The following revisions are being proposed.

Miscellaneous Corrections – 10 CFR Parts 37, 40, 70, and 71: The objective of this rule is to make miscellaneous corrections concerning office references and a phone number, remove and correct division titles, and remove a follow up reporting instruction. (Sections 2, 4, and 12)

Miscellaneous Corrections – 10 CFR Parts 1, 2, 34, 37, 50, 71, 73, and 140: The objective of this rule is to update descriptions of agency organizations and functions; correct cross reference, typographical, and grammatical errors; and add a certification recipient and clarifying language. (Sections 3, 4, and 12)

Miscellaneous Corrections – 10 CFR Parts 2, 21, 37, 50, 52, 73, and 110: The objective of this rule is to remove obsolete language and correct references, a typographical error, mailing, email, and web page addresses, grammatical errors, a division title, and a division address and title. (Section 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 for General Clean Up --** Changes include deletion and revision of a small number of radioactive material healing arts definitions, correction of references found in RH-7083.b., and addition of form numbers to RH-23.

#### RECOMMENDATION

We recommend that the proposed amendments to the Rule for the Control of Sources of Ionizing Radiation be approved as proposed by the Department.

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

	EPARTMENT/AGENCY Arkansas Departme	ent of Health			
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		O. (501) 280-4993	E-MAIL bernard.bevill@arkansas.gov		
	AME OF PRESENTER AT COMMITTEE		eles Thompson		
	RESENTER E-MAIL Charles. Thompson@arl		Thompson		
		INSTRUCTION	ONS		
Α.	Please make copies of this form for futur	e use.	Way Calmy antistive on at immediatory on side at		
В.	Please answer each question completely i	using layman term	s. You may use additional sheets if necessary.		
C.	If you have a method of indexing your ru	les, please give the	e proposed citation after "Short Title of this		
	Rule" below.	haledel yhtaeta e	suscentinent does, and the mark-up copy should b		
E.	copies of the proposed rule and required	re and Financial I documents. Mail	mpact Statement attached to the front of two (2) 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? Rules	s for Control of So	ources of Ionizing Radiation		
2.	What is the subject of the proposed rule?	The proposed ful	le pertains to possession and use of x-ray machines, radioactive material in the state of Arkansas.		
3.	Is this rule required to comply with a fed	eral statute, rule,	or regulation? Yes☑ No ☐		
	If yes, please provide the federal rule, regulation, and/or statute citation.				
	Section 274 of the Atomic Energy Act, 1954, As Amended				
	Rules councing radicactive material and x-ray machines are undersoing revision due to Act 208 of 2021				
	el due to teulmological advances.				
1.	Was this rule filed under the emergency p	provisions of the A	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 permar	nent provisions of the Administrative Procedure		
	Act? Yes No	1	,		
	Act: IesNO				

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Does this reneal an existing	rule? Yes No If yes, a copy of the repealed rule is to be included with your
	f it is being replaced with a new rule, please provide a summary of the rule giving
an explanation of what the	rule does.
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the existing rule and a sum	existing rule? Yes No If yes, please attach a mark-up showing the changes mary of the substantive changes. Note: The summary should explain what the nark-up copy should be clearly labeled "mark-up."
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	by Arkansas Code § 25-19-108(b).		
	www.healthy.arkansas.gov		
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	SEEPHONE NO. (501) 661-2101 FAXING. (501) 281-4953 EMAIL: ancide mendendisciplinates gov.		
).	Will a public hearing be held on this proposed rule? Yes \( \subseteq No \( \subseteq \) If yes, please complete the following:		
	CORT TITLE OF THIS RULE Rules for Council of Sources of Contains Radiation :staG		
	Does this proposed, unsended, or repealed rule have a financial impact? Yes New :: smiT		
	Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and  :encountering a content of the four way consequence or and another to the value.		
0.	When does the public comment period expire for permanent promulgation? (Must provide a date.)  09/30/2021		
1.	What is the proposed effective date of this proposed rule? (Must provide a date.)  12/01/2021		
	Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice.		
	Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25 15-204(e).		
	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.		
	X-ray registrants or vendor service registrants may comment.		
	d) Venetice the reason is within the scope of the agency's stantony assentity, and if so, please expining		

Revised June 2019

### FINANCIAL IMPACT STATEMENT

## PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health DIVISION Center for Health Protection
ERSON COMPLETING THIS STATEMENT Angela Minden
<b>ELEPHONE NO.</b> (501) 661-2301 <b>FAX NO.</b> (501) 280-4993 <b>EMAIL:</b> angela.minden@arkansas.gov
To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and financial wo (2) copies with the Questionnaire and proposed rules.
HORT TITLE OF THIS RULE Rules for Control of Sources of Ionizing Radiation
. Does this proposed, amended, or repealed rule have a financial impact? Yes No
. 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 □
. 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;
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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, pleas explain; and
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d) Whether the reason is within the scope of the agency's statutory authority, and if so, please explain.
Revised June 2

a) \	What is the cost to implement the	federal rule or regulation	on?		
9	Current Fiscal Year	Next Fiscal	Year		
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	Federal Funds		nds		
(	Cash Funds	Coch Funde			
5	Special Revenue	Special Rev	enue		
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4.	Total\$ 0.00	Total			
b) <b>V</b>	What is the additional cost of the s	state rule?			
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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 V

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.