EXHIBIT E

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

SUBJECT: Control of Sources of Ionizing Radiation

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

- **Physical Protection of Byproduct Material** – The objective of this rule is to provide reasonable assurance of preventing theft or diversion of Category 1 and Category 2 quantities of radioactive material. Category 1 and Category 2 thresholds are based on the quantities established by the International Atomic Energy Agency (IAEA) in its Code of Conduct on the Safety and Security of Radioactive Sources, which the NRC endorses. The regulations also include security requirements for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. The rule affects any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material, any licensee that transports these materials using ground transportation, and any licensee that transports small quantities of irradiated reactor fuel.

(Sections 2, 3, 4, 9, and a new Section 12)

- **Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions** – The purpose of this amendment is to require that the initial distribution of source material to exempt persons or to general licensees be explicitly authorized by a specific license, which includes new reporting requirements. The rule is intended to provide timely information on the types and quantities of source material distributed for use either under exemption or by general licensees. In addition, the rule modifies the existing possession and use requirements of the general license for small quantities of source material to better align the requirements with current health and safety standards. Finally, the rule revises, clarifies, or deletes certain source material exemptions from licensing to make the exemptions more risk informed. This rule affects manufacturers and distributors of certain products and materials containing source material and certain persons using source material under general license and exemptions from licensing.
(Section 2)

- **Safeguards Information – Modified Handling Categorization, Change for Materials Facilities** – The objective of this rule is to remove the Safeguards Information – Modified Handling (SGI-M) designation of the security-related information for large irradiators, manufacturers and distributors, and for transport of Category 1 quantities of radioactive material. The SGI-M designation will also be removed from security-related

information for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. These types of security-related information will no longer be designated as SGI-M and will be protected under the physical protection of byproduct material regulations.

Also, the sections not in conjunction with a particular NRC regulation amendment have been added, revised, or deleted in keeping with NRC compatibility.

PUBLIC COMMENT: A public hearing was held on this rule on June 4, 2015. The public comment period expired June 4, 2015. The Department received the following public comment:

U.S. Nuclear Regulatory Commission

COMMENT: Arkansas' regulation states, "Special nuclear material means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Department, pursuant to the provisions of section 51 of the act, determines to be special nuclear material . . .". Arkansas has changed the word "Commission" to "Department". As the State cannot determine what is considered special nuclear material under the AEA, Arkansas needs to retain the reference to the NRC. Arkansas needs to make the above change in order to meet the Compatibility Category A designation assigned to 10 CFR Parts 70.4 and 20.1003.
RESPONSE: "Department" was made to say "Commission" in the added special nuclear material definition found in RH-200 and in the current special nuclear material definition found in RH-1100.

The proposed effective date for the final rule March 1, 2016.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: This proposed rule impacts any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material and any licensee that transports these materials using ground transportation. Estimated increased cost is dependent on a multitude of factors.

Regarding the financial impact, the written findings include the following:

1) The potential financial impact regarding a portion of this rule package is due to a U.S. Nuclear Regulatory Commission amendment of its regulations to establish security requirements for the use and transport of Category 1 and Category 2 quantities of radioactive material. As an Agreement State, the State of Arkansas is required to have regulations that are compatible with NRC regulations. The NRC considers the aforementioned quantities of radioactive material to be risk significant and, therefore, to warrant additional protection. Category 1 and Category 2 thresholds are based on the quantities established by the International Atomic Energy Agency (IAEA) in its Code of Conduct on the Safety and Security of Radioactive Sources, which the NRC endorses.

The objective of this rule is to provide reasonable assurance of preventing theft or diversion of Category 1 and Category 2 quantities of radioactive material. The regulations also include security requirements for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. The rule affects any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material, any licensee that transports these materials using ground transportation, and any licensee that transports small quantities of irradiated reactor fuel.

2) Pursuant to Section 274 of the Atomic Energy Act, 1954, the State of Arkansas, as a function of our Agreement State program, must have regulations that satisfy the compatibility and health and safety categories established in the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200.

3) The NRC has long participated in efforts to ensure radioactive source protection and security. The terrorist attacks of September 11, 2001, heightened concerns about the use of risk-significant radioactive materials in a malevolent act. Such an attack is of particular concern because of the widespread use of radioactive materials in the United States by industrial, medical, and academic institutions. The theft or diversion of risk-significant quantities of radioactive materials could lead to their use in a radiological dispersal device (RDD) or a radiological exposure device (RED). Subsequently, the NRC issued various sets of orders to certain licensees, and, in turn, each Agreement State was required to issue legally binding requirements to impose enhanced security measures, identical to one of the NRC's sets of orders called the Increased Control Orders issued in 2005, for licensees under that State's regulatory jurisdiction. Agreement States also had to issue legally binding requirements consistent with a certain fingerprinting and FBI criminal history records checks order issued by the NRC in 2007.

The security requirements in the proposed rule are similar to the requirements imposed on licensees through the NRC's previously issued orders/Agreement State legally binding requirements. The NRC has determined that it is preferable to regulate through rulemaking rather than order because notice and comment rulemaking is an open and transparent process that facilitates public participation. In developing the final rule, the NRC considered, among other things, the various orders, lessons-learned during implementation, the recommendations from an Independent Review Panel and a Materials Working Group, and stakeholder comments. In NRC's final rule, some of the orders were deleted or revised, or new requirements were issued.

4) This rule would impose the minimum requirements that the NRC believes are necessary to adequately protect public health and safety. The rule provides some flexibility in the particular measures that a licensee can choose to employ in order to demonstrate compliance. Licensees have already implemented the bulk of the rule's requirements in response to previous NRC orders/Agreement State legally binding requirements. Some of the new proposed requirements may already be implemented if the licensee had chosen in the past to voluntarily enact the requirement, e.g., the developing of access authorization program or security program procedures.

The total cost to some licensees may be higher or lower than to others. The actual total cost depends on a multitude of factors including, but not limited to: the number of individuals granted unescorted access, the number of procedures that must be developed, the particular security measures that are used to meet the requirement, the extent of training to be given, and the number of Category 1 or Category 2 sources possessed and the location of the sources relative to other sources. Some of the actions required of the licensees may be conducted by lower paid employees, such as clerical staff. Also, over half of the Arkansas licensees affected by this portion of the proposed rule would be considered "out-of-state" licensees and therefore compliance with the NRC's amendment would have to be dually demonstrated. As such, certain costs/financial impact would be somewhat shared between States.

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

6) The State of Arkansas currently has no regulations specifically addressing the physical protection of Category 1 and Category 2 quantities of radioactive material.

7) Section 12 of the Rules and Regulations for Control of Sources of Ionizing Radiation regarding the physical protection of Category 1 and Category 2 quantities of radioactive material 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, special nuclear material, or devices or equipment utilizing such material". Ark. Code Ann. § 20-21-213 provides in addition that this rule "shall provide for amendment, suspension, or revocation of licenses".

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

Ark. Code Ann. § 20-21-204 provides that the Department may assess a civil penalty not to exceed five thousand dollars ($5,000) to a person who violates any licensing or registration requirement issued by the Department or who violates the provisions of Ark. Code Ann. § 20-21-201 et seq. or the Department's rules.

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

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

DEPARTMENT/AGENCY Arkansas Department of Health

DIVISION Center for Health Protection

DIVISION DIRECTOR Donnie Smith

CONTACT PERSON Bernard Bevill

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

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

NAME OF PRESENTER AT COMMITTEE MEETING Robert Brech

PRESENTER E-MAIL robert.brech@arkansas.gov

INSTRUCTIONS

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

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

****

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

2. What is the subject of the proposed rule? These Regulations pertain to the use of radioactive material in the state of Arkansas. As an Agreement State with the U.S. Nuclear Regulatory Commission (NRC), Arkansas must have regulations that are compatible with the NRC. The proposed changes reflect NRC compatibility requirements.

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. Lastly, 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: June 4, 2015
Time: 10:00 a.m.
Place: 5800 West 10th Street, Room 906, Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
June 4, 2015

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
published by September 1, 2015 with an implementation/effective date of March 1, 2016

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

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health

DIVISION Center for Health Protection

PERSON COMPLETING THIS STATEMENT Angela Minden

TELEPHONE NO. (501) 661-2528 **FAX NO.** (501) 280-4407 **EMAIL:** angela.minden@arkansas.gov

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

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

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☒ No ☐

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes ☒ No ☐

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☒ No ☐

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

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

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

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

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

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

   (a) What is the cost to implement the federal rule or regulation?

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

Total	0	Total	0

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

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

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

Current Fiscal Year

$ 12068

Next Fiscal Year

$ 10972

The proposed rule impacts any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material and any licensee that transports these materials using ground transportation. Estimated increased cost is dependent on a multitude of factors. Please see Written Findings.

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

$ 0

Next Fiscal Year

$ 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.

WRITTEN FINDINGS

regarding April 2015 Proposed Revisions to
Rules and Regulations for Control of Sources of Ionizing Radiation
pursuant to A.C.A. §25-15-204(e)(4)

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

1) The potential financial impact regarding a portion of this rule package is due to a U.S. Nuclear Regulatory Commission amendment of its regulations to establish security requirements for the use and transport of Category 1 and Category 2 quantities of radioactive material. As an Agreement State, the State of Arkansas is required to have regulations that are compatible with NRC regulations. The NRC considers the aforementioned quantities of radioactive material to be risk significant and, therefore, to warrant additional protection. Category 1 and Category 2 thresholds are based on the quantities established by the International Atomic Energy Agency (IAEA) in its Code of Conduct on the Safety and Security of Radioactive Sources, which the NRC endorses.

   The objective of this rule is to provide reasonable assurance of preventing theft or diversion of Category 1 and Category 2 quantities of radioactive material. The regulations also include security requirements for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. The rule affects any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material, any licensee that transports these materials using ground transportation, and any licensee that transports small quantities of irradiated reactor fuel.

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7) Section 12 of the Rules and Regulations for Control of Sources of Ionizing Radiation regarding the physical protection of Category 1 and Category 2 quantities of radioactive material will be reviewed at least every ten years to determine, based upon the evidence, whether there remains a need for the rule.

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

APRIL 2015 REGULATION PACKAGE

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

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Also, the following sections not in conjunction with a particular NRC regulation amendment have been added, revised, or deleted in keeping with NRC compatibility as well:

RH-102.	License Requirement *(Purpose and Scope)*
RH-200.	Definition of "principal activities"
RH-200. and 1100.	Definition of "special nuclear material"
RH-406.	Special Requirements for Specific Licenses of Broad Scope
RH-501.	Condition of Transfer *(transfer of radioactive material)*
RH-600.	Records *(receipt, transfer, and disposal of radioactive material)*
RH-1303.b.3.	Posting of Very High Radiation Areas
RH-1500.h.1.	Records of waste disposal
RH-1800.a. and b. (RH-405.f. moved to RH-1800.b.2. and revised)	General Provisions *(Purpose and scope; Application for a specific license; Specific licenses for industrial radiography)*
RH-7013.a.	Specific Licenses for Irradiators *(specific license approval)*
RH-8420.	Release of Individuals Containing Radioactive Drugs or Implants *(authorizing release of individuals administered unsealed radioactive material or implants containing radioactive material)*
RH-8552.b.	Safety Precautions *(regarding individuals hospitalized for radiopharmaceutical therapy)*
RH-8603.	Safety Instruction *(regarding individuals hospitalized for implant therapy)*
RH-8710.	Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material
RH-8803.	Reports of Patient Departure Prior to Authorized Release *(without authorization under RH-8420.)*
RH-8804.	Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material
RH-104., 1003., 3003., 4003., 5004., 7003., 8006., 10003.,	Communications *(Department/Radiation Control address)*
RH-105., 1104., 3006., 4004., 5005., 7005., 8007., 10004.	Interpretations *(by Department Director or designee)*
RH-304., 1991., 2000., 3200., 5600.e., 7017.a., 8026., 10005.	Specific Exemptions *(granting of exemptions by the Department)*
RH-751., 2001.	Additional Requirements *(imposed as necessary to minimize danger to public health and safety or property)*
RH-601.a., 5602.	Inspections
RH-700.a., 2110.a., 3700., 5700.a., 7091.a., 8900.a., 10500.a.	Violations
RH-3700.b., 8900.b., 10500.b.	Impounding