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SECTION 2. LICENSING OF RADIOACTIVE MATERIALS

PART A. GENERAL

RH-106. Completeness and accuracy of information.

- a. Information provided to the Department by an applicant for a license or by a licensee or information required by statute or by the Department's regulations. orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.
- Each applicant or licensee shall notify the Department of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or property. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Department of information that the applicant or licensee has identified as having a significant implication for public health and safety or property. Notification shall be provided to the Department within two (2) working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Department by other reporting or updating requirements.

RH-1511.RH-107.Deliberate Misconduct.

- a. Any licensee, registrant, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee or registrant, certificate of registration holder, or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee, registrant, or certificate of registration holder, or applicant for a license; registration, or certificate of registration, who knowingly provides to any licensee, registrant, applicant, certificate holder, contractor or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's, certificate holder's, or applicant's activities subject to this Section, may not:
 - 1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Department; or

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- 2. Deliberately submit to the Department, a licensee, registrant, certificate of registration holder, an applicant, or a licensee's, registrant's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.
- b. A person who violates RH-1511. paragraph a.1. or a.2. of this section may be subject to enforcement action in accordance with the procedures in RH-2110 700.
- c. For purposes of RH 1511. <u>paragraph</u> a.1. <u>of this section</u>, deliberate misconduct by a person means an intentional act or omission that the person knows:
 - 1. Would cause a licensee, registrant, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Department; or
 - 2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, certificate of registration holder, applicant, contractor, or subcontractor.

RH-1068.- RH-199. Reserved.

PART B. DEFINITIONS

RH-200.

Definitions.

Decommission - to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

1. Release of the property for unrestricted use and termination of the license: or

2. Release of the property under restricted conditions and termination of the license.

Licensed material - Source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general license provided by regulation or a specific license issued by the Department.

Sealed source - Radioactive material that is permanently bonded or fixed encased in a capsule or matrix designed to prevent release and dispersal leakage or escape of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

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PART C. EXEMPTIONS

RH-301. Radioactive Material Other Than Source Material.

a. Exempt concentrations. ...

4. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section RH-301.a., or equivalent regulations of the Nuclear Regulatory Commission or any Agreement State, except in accordance with a license issued by the NRC pursuant to 10 CFR 32.11.

PART D. LICENSES

RH-401. General Licenses - Source Material.

1.

- a. Small quantities of source material. ...
 - A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:
 - A. No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph a.1.A. may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of March 1, 2016, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Department takes final action on a pending license amendment or application for a specific license submitted on or before March 1, 2017, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31,

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2017, or until the Department takes final action on a pending <u>license</u> amendment or application for a specific license submitted on or before March 1, 2017, for a specific license for such material; and

- B. No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under <u>this</u> paragraph a.1.B. may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under <u>this</u> paragraph a.1.B. unless it is accounted for under the limits found in paragraph a.1.A. <u>of this section</u>; or
- C. No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under <u>this</u> paragraph a.1.C.; or
- D. No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph a.1.D. may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.
- 2. Any person who receives, possesses, uses, or transfers source material in accordance with the general license in paragraph a. of this section:
 - A. Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Department in a specific license.
 - B. Shall not abandon such source material. Source material may be disposed of as follows:
 - A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of <u>this</u> paragraph a.2.B.i. is exempt from the requirements to obtain a license under this Section to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued pursuant to these Regulations; or

RH-401.a.2. (Cont'd)

i.

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- ii. In accordance with RH-1400.
- C. Is subject to the provisions in RH-102., <u>RH-104.</u>, <u>105.</u> through <u>RH-107.</u>, <u>RH-200.</u>, <u>1100.</u>, <u>1511.</u>; RH-409.a. through d.; <u>RH-500.</u> and <u>501</u> Part E to Section 2.; <u>RH-1502.e. through g.</u>, <u>RH-</u>600. through 602 <u>3</u>.; <u>RH-416.</u>; and RH-700. ...
- 5. No person may initially transfer or distribute source material to persons generally licensed under paragraph a.1.A. or a.1.B. of this section, or equivalent regulations of the Nuclear Regulatory Commission or of an Agreement State, unless authorized by a specific license issued in accordance with RH-405.b.1. or equivalent provisions of the NRC or of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by paragraph a.1. of this section before March 1, 2016, without specific authorization may continue for one year beyond this date. Distribution may also be continued until the Department takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before August 27, 2014 March 1, 2017.

c. Certain industrial products or devices. ...

3.

- A. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by paragraph c.1. of this section shall file Department form RC FORM 513. "Registration Certificate Use of Depleted Uranium Under General License." with the General License Registration Program, Radiation Control Section, Arkansas Department of Health. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. Persons possessing depleted uranium pursuant to the general license in paragraph c.1. of this section as of March 1, 2016 shall register the depleted uranium with the Department on or before March 1, 2017. The general license shall furnish on the form the following information and such other information as may be required by the form: ...
 - B. The general licensee possessing or using depleted uranium under the general license established by paragraph c.1. of this section shall report in writing to the Department any changes in information originally furnished by the licensee in Department form <u>RC FORM</u> <u>513</u>, "Registration Certificate Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change. ...

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Shall transfer or dispose of such depleted uranium only by transfer С. in accordance with the provisions of Part E to Section 2 and RH-1400. In the case where the transferee receives the depleted uranium pursuant to the general license established by paragraph c.1. of this section, the transferor shall furnish the transferee a copy of paragraph c. of this section and a copy of Department form RC FORM 513. "Registration Certificate - Use of Depleted Uranium Under General License." In the case where the transferee receives the depleted uranium pursuant to a general license of the Nuclear Regulatory Commission or an Agreement State that is equivalent to paragraph c., the transferor shall furnish the transferee a copy of paragraph c. and a copy of Department form RC FORM 513. "Registration Certificate - Use of Depleted Uranium Under General License," accompanied by a note explaining that use of the product or device is regulated by the governing agency, the agency who has jurisdiction where the product or device will be in use, under requirements substantially the same as those in paragraph c.; and ...

RH-402. General Licenses - Radioactive Material Other Than Source Material.

- a. Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere. ...
- c. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in RH-402.a.: ...
 - 9. Shall transfer the device to another general licensee only if:
 - A. The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of RH-402.<u>a.-e.</u>, RH-600., RH-1501.. and RH-1502., and any safety documents identified in the label of the device. Within thirty (30) days of the transfer, the transferor shall report to: ...
 - 13. A. Shall register, in accordance with RH-402.c.13.B. and C. devices containing at least ten (10) mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, one (1) mCi (37 MBq) of cobalt-60, 0.1 mCi (3.7 MBq) of radium-226, one (1) mCi (37 MBq) of nickel-63, or one (1) mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under RH-402.c.13.C., represents a separate general licensee and requires a separate registration and fee. ...

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- 15. May not hold devices that are not in use for longer than two (2) years twenty-four (24) months following the last principal activity use.
 - <u>A.</u> If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by RH-402.c.2. need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use.
 - B. Devices kept in standby for future use are excluded from the two (2) year twenty-four (24) month time limit if the Department approves a plan for future use submitted by the licensee. Licensees shall submit plans at least thirty (30) days prior to the end of the twenty-four (24) months of nonuse.
 - C. The general licensee <u>shall</u> performs quarterly physical inventories of these devices while they are in standby. <u>Records of the quarterly</u> <u>physical inventories shall be maintained for inspection by the</u> Department for five (5) years after they are made. ...
- e. The general license provided in RH-402.a. is subject to the provisions of RH 60., RH-409., RH-416., RH-500., RH 501., <u>Part E to Section 2.</u> RH-600., RH-601., RH-602., <u>RH-603.</u>, <u>RH-700.</u>, RH-751., RH 4012., Section 3^{6/} and Section 4.

f. 4. Luminous safety devices in aircraft.

- A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than ten (10) curies (<u>370</u> <u>GBq</u>) of tritium or 300 millicuries (11.1 GBq) of promethium-147 and that each device has been manufactured, assembled, or imported initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer, assembler, or initial transferor by the U.S. Nuclear Regulatory Commission Department pursuant to RH-405.h. or each device has been manufactured or assembled in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department U.S. Nuclear Regulatory Commission or any Agreement State to the manufacturer or assembler of such device pursuant to licensing equivalent requirements equivalent to those in Section 32.53 of 10 CFR Part 32.
- 2. Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in RH-402.f.1. are exempt from the

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requirements of Section 3, except that they shall comply with the provisions of RH-1501. and RH-1502.

- This general license does not authorize the manufacture, assembly, or repair, import. or export of luminous safety devices containing tritium or promethium-147.
- 4. This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.
- 5. The general license provided in this paragraph f.<u>1. of this section</u> is subject to the provisions of RH-56., RH-60., RH-409., RH-416., RH-500., RH-501., <u>Part E to Section 2.</u> RH-600., RH-601., RH-602., <u>RH-603., RH-700., RH-751., RH-4012.</u> and Section 4.

g. 4. Calibration and reference sources.

- 1. A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with <u>the</u> provisions of subparagraphs <u>g.4</u>. and <u>g.5</u>. of this paragraph g. section, americium-241 in the form of calibration or reference sources:
 - A. Any person who holds a specific license issued by the Department which authorizes him to receive, possess, receipt, possession, use, and transfer of radioactive material; and
 - B. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, receipt, possession, use, and transfer of special nuclear material.
- 2. A general license is hereby issued to <u>own.</u> receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subparagraphs <u>g.4</u>. and <u>g.5</u>. of this paragraph g. <u>section</u> to any person who holds a specific license issued by the Department which authorizes him to receive, possess, receipt, possession, use, and transfer <u>of</u> radioactive material.
- 3. A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of subparagraphs g.4. and g.5. of this paragraph g. section to any person who holds a specific license issued by the Department which authorizes him to receive, possess, receipt, possession, use, and transfer of radioactive material.
- 4. The general licenses in subparagraphs 1. and 2. g.1. through g.3. of this paragraph g. section apply only to calibration or reference sources which

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have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or importer initial transferor of the sources by the U.S. Nuclear Regulatory Commission Department pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 RH-405.i. or which have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued to the manufacturer by the Department U.S. Nuclear Regulatory Commission or any Agreement State pursuant to licensing equivalent requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 RH-405.i.

- 5. The general licenses in subparagraphs 1. and 2. g.1. through g.3. of this paragraph g. section are subject to the provisions of RH-60., RH-301.a.4. RH-409., RH-416., RH 500., RH 501., Part E to Section 2. RH-600., RH-601., RH-602. through RH-603., RH-700. RH-751., RH-4012., Section 3. and Section 4. In addition, persons who own, receive, acquire, possess, use and or transfer one (1) or more calibration or reference sources pursuant to these general licenses:
 - A. Shall not possess at any one time, at any one location of storage or use, more than five (5) microcuries (185 kBq) of americium-241, five (5) microcuries (185 kBq) of plutonium, or five (5) microcuries (185 kBq) of radium-226 in such sources;
 - B. Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

"The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL THIS SOURCE CONTAINS AMERICIUM-241 (or [PLUTONIUM, or <u>OR</u> RADIUM-226, as appropriate)]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

RH-402.g.5. (Cont'd)

(name of manufacturer or importer initial transferor)"

C. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Department, the

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U.S. Nuclear Regulatory Commission, or an Agreement State to receive the source;

- D. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and
- E. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.
- 6. These general licenses do not authorize the manufacture. import, or export of calibration or reference sources containing americium-241, plutonium, or radium-226.

h. Ownership of radioactive byproduct material.

A general license is hereby issued to own radioactive <u>byproduct</u> material without regard to quantity. Notwithstanding any other provisions of these Regulations, this <u>a general licensee under this paragraph</u> does is not authorized the to manufacture, production produce, transfer, receipt receive, possession possess or use import or export of radioactive byproduct material-, except as authorized in a specific license.

i. Ice detection devices.

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (<u>1.85 MBq</u>) of strontium-90 and <u>that</u> each device has been manufactured or imported initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or initial transferor by the U.S. Nuclear Regulatory Commission Department pursuant to RH-405.k. or each device has been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department <u>U.S.</u> <u>Nuclear Regulatory Commission</u> or any Agreement State to the manufacturer of such device pursuant to licensing equivalent requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

RH-402.i. (Cont'd)

- 2. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in subparagraph <u>i.</u>1. of this paragraph i. section:
 - A. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device,

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discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license or equivalent licensing document from the Department, the U.S. Nuclear Regulatory <u>Commission</u>, or any Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of RH-1400;

- B. Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon;
- C. Are exempt from the requirements of Section 3 except that such persons shall comply with the provisions of RH-1400., RH-1501., and RH-1502.
- 3. This general license does not authorize the manufacture, assembly, disassembly, or repair, <u>import</u>, or <u>export</u> of strontium-90 in ice detection devices.
- The general license in RH-402.i. paragraph i.1. of this section is subject to the provisions of RH-60., RH-409., RH-416., RH-500., RH-501., Part E to Section 2. RH-600., RH-601., RH-602., RH-603., RH-700., RH-751., RH-4012. and Section 4.

j. Products containing radium-226. ...

2. Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in RH-402.j.1. are exempt from the provisions of Section 3. (including RH-1502.e. through-g.), and RH-600. and RH-601., to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this Section.

k. Use of radioactive material for certain *in vitro* clinical or laboratory testing.^{8/}

2. No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by RH-402.k.1. until the individual has filed Department form <u>RC FORM 512</u>. "Registration Certificate - *In Vitro* Testing with Radioactive Material under General License," with the General License Registration Program, Radiation Control Section, Arkansas Department of Health and received from the Department a validated copy of this form with registration number assigned or until he has been authorized pursuant to RH-8013. to use radioactive material under the general license in RH-402.k. The registrant shall furnish

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on the above form the following information and such other information as may be required by that form: ...

5. The registrant possessing or using radioactive material under the general license of RH-402.k.1. shall report in writing to the Radiation Control Section Chief, any changes in the information furnished by him in the Department form <u>RC FORM 512.</u> "Registration Certificate - *In Vitro* Testing with Radioactive Material under General License." The report shall be furnished within thirty (30) days after the effective date of such change.

m. Ownership of special nuclear material.

A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of this Section these Regulations, a general licensee under RH 402. this paragraph is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

RH-404. General Requirements for the Issuance of Specific Licenses.

A license application will be approved if the Department determines that:

a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with Section 3 of these Regulations in such a manner as to minimize danger to public health and safety or property;

RH-405. Special Requirements for the Issuance of Certain Specific Licenses. ...

- a. Licensing of the manufacture and initial transfer of industrial products and devices containing depleted uranium. ...
 - 2. Conditions of specific licenses issued pursuant to RH-405.a.1.

Each person licensed pursuant to RH-405.a.1. shall: ...

D. i. Furnish a copy of the general license contained in RH-401.c. and a copy of Department form <u>RC FORM 513</u>.
"Registration Certificate - Use of Depleted Uranium Under General License." to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in RH-401.c.; or

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- ii. Furnish a copy of the general license contained in the NRC's or Agreement State's regulation equivalent to RH-401.c. and a copy of the NRC's or Agreement State's certificate, or alternately, furnish a copy of the general license contained in RH-401.c. and a copy of Department form RC FORM 513. "Registration Certificate - Use of Depleted Uranium Under General License," to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license of the NRC or an Agreement State. If a copy of the general license in RH-401.c. and a copy of Department form RC FORM 513. "Registration Certificate - Use of Depleted Uranium Under General License," are furnished to such person, they shall be accompanied by a note explaining that use of the product or device is regulated by the NRC or an Agreement State. depending on which agency has jurisdiction where the product or device will be in use, under requirements substantially the same as those in RH-401.c.; ...
- e. Licensing of the manufacture or initial transfer of devices to persons generally licensed under RH-402.a. ...

4.

- A. If a device containing radioactive material is to be transferred for use under the general license contained in RH-402.a., each person that is licensed under RH-405.e. shall provide the information specified in this paragraph <u>e.4.A. of this section</u> to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:
 - i. A copy of the general license contained in RH-402.a.<u>-e.</u>; if paragraphs RH-402.c.2. through c.4. or RH-402.c.13. do not apply to the particular device, those paragraphs may be omitted.
 - ii. A copy of RH-402., RH-600., RH-1501., and RH-1502.,
 - iii. A list of the services that can only be performed by a specific licensee;
 - iv. Information on acceptable disposal options including estimated costs of disposal; and

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- v. An indication that the Department's policy is to seek high civil penalties for improper disposal.
- B. If radioactive material is to be transferred in a device for use under an equivalent general license of <u>the NRC or</u> an Agreement State, each person that is licensed under RH-405.e. shall provide the information specified in this sub-subparagraph <u>e.4.B. of this section</u> to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:
 - i. A copy of the NRC or Agreement State's regulations equivalent to RH-402.a.-e., RH-402., RH-600., RH-1501., and RH-1502. or a copy of RH-402.a.-e., RH-402., RH-600., RH-1501., and RH-1502. If a copy of a non-governing agency's regulations is provided to a prospective general licensee in lieu of the governing agency's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the governing agency, the agency who has jurisdiction where the device will be in use. If certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.
 - A list of the services that can only be performed by a specific licensee;
 - iii. Information on acceptable disposal options including estimated costs of disposal; and
 - iv. The name or title, address, and phone number of the contact at the Department, NRC, or Agreement State from which additional information may be obtained.

f. Deleted. See RH 1800.b.2. Licensing the distribution of radioactive material in exempt quantities.

Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements under RH-305, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, may be obtained only from the NRC pursuant to 10 CFR 32.18.

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g. Licensing of the introduction of radioactive material into products in exempt concentrations.

No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under RH-301.a., or equivalent regulations of <u>the U.S. Nuclear Regulatory Commission or an</u> Agreement State, except in accordance with a license issued <u>by the NRC</u> pursuant to 10 CFR 32.11.

RH-408. Issuance of Specific Licenses.

- a. Upon a determination that an application meets the requirements of the Act and these Regulations of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate and necessary to effectuate the purposes of the Act.
- b. The Department may incorporate in any license 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 licensed 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 inspection of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and these Regulations thereunder; and
 - 3. Prevent loss or theft of licensed material.

RH-409. Specific Terms and Conditions of Licenses. ...

- c. Each person licensed by the Department pursuant to these Regulations shall confine their his use and possession of the material licensed to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to these Regulations shall carry with it the right to receive, acquire, receive title to, own, and 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.
- d. The Department may incorporate, in any license issued pursuant to these Regulations, at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's

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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 thereunder.
- 3. Prevent loss or theft of licensed material.

RH-410. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas. ...

- e. Coincident with the notification required by RH-410.d., the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to RH-409.h. in conjunction with a license issuance or renewal or as required by RH-410. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to RH-410.g.4.E.
 - 1. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this regulation becomes effective July 1, 2002.
 - 2. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Department. ...
 - As the final step in decommissioning, the licensee shall:
 - Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed, <u>up-to-date RC FORM 530 NRC Form</u> 314, "Certificate of Disposition of Materials," or equivalent information; and ...

PART E. TRANSFER OF MATERIAL

RH-501. Conditions of Transfer.

j.

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- a. Except as otherwise provided in the license and subject to the provisions of paragraphs b. and c. of this section, any licensee may transfer radioactive material, subject to acceptance by the transferee, to:
 - 1. The Department;
 - 2. The U.S. Department of Energy;
 - 3. Any person exempt from the licensing requirements of the Act and these Regulations, to the extent permitted under such exemption;
 - 4. Any person in an Agreement State, subject to the jurisdiction of that State, who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemption:
 - 5. Any person in U.S. Nuclear Regulatory Commission (NRC) jurisdiction, subject to the jurisdiction of the NRC, who has been exempted from the licensing requirements and regulations of the NRC, to the extent permitted under such exemption;
 - 4. 6. Any person authorized to receive such material under terms of a general license or its equivalent or <u>a</u> specific license or <u>their</u> equivalents licensing document issued by the Department, the U.S. Nuclear Regulatory Commission (NRC), or any Agreement State or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department, or an Agreement State; or
 - 5. 7. Any other person As otherwise authorized by the Department in writing.
- b. Before transferring radioactive material to a specific licensee of the Department, the NRC, or an Agreement State, or to a general licensee who is required to register with the Department, the NRC, or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. ...
- d. The transferor shall keep a copy of the verification documentation as a record for three (3) years.

RH-502. **Preparation and Transport**.

Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of RH-3004. Section 4 of these Regulations.

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PART F. RECORDS, <u>REPORTS</u> INSPECTIONS, AND TESTS

RH-600. Records.

a. Receipt, transfer, and disposal.

Each person who receives radioactive material pursuant to a license issued pursuant to the regulations in this Section, Part I to Section 3, Part J to Section 3, and Sections 7, 8, and 9 of these Regulations shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

- 1. The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three (3) years following transfer or disposal of the material.
- 2. The licensee who transferred the material shall maintain each record of transfer for three (3) years after each transfer unless a specific requirement in another part of these Regulations dictates otherwise.
- 3. The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Department terminates each license that authorizes disposal of the material.
- 4. If radioactive material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques (such as first-in-first-out) to make the records that are required by this Section account for 100 percent (100%) of the material received.

b. **Record retention periods.**

- 1. The licensee shall retain each record that is required by the regulations in this Section, Part I to Section 3, Part J to Section 3, and Sections 7, 8, and 9 of these Regulations or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.
- 2. If there is a conflict between the Department's regulations in this Section, Part I to Section 3, Part J to Section 3, and Sections 7, 8, and 9 of these Regulations, license condition, or other written Department approval or

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authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this Section, Part I to Section 3, Part J to Section 3, and Sections 7, 8, and 9 of these Regulations for such records shall apply unless the Department, pursuant to RH-304., has granted a specific exemption from the record retention requirements specified in the regulations in this Section, Part I to Section 3, and Sections 7, 8, and 9 of these Regulations.

c. <u>Record maintenance.</u>

- 1. Records which must be maintained pursuant to Each record required by this Section, Part I to Section 3, Part J to Section 3, and Sections 7, 8, and 9 of these Regulations must be legible throughout the specified retention period. The record may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Department regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.
 - If there is a conflict between the Department's regulations in this Section, Part I to Section 3, Part J to Section 3, and Sections 7, 8, and 9 of these Regulations, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this Section, Part I to Section 3, Part J to Section 3, and Sections 7, 8, and 9 of these Regulations for such records shall apply unless the Department, pursuant to RH 304., has granted a specific exemption from the record retention requirements specified in the regulations in this Section 3, Part J to Section 3, and Sections 7, 8, and 9 of these Regulations
- d. Prior to license termination, each licensee <u>previously or currently</u> authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Department:
 - 1. Records of disposal of licensed material made under RH-1401., RH-1402., a previous RH-1403. that authorized certain burials^{11/}, RH-1404., RH-1405., RH-1408.; and
 - 2. Records required by RH-1500.c.2.D.
- e. If licensed activities are transferred or assigned in accordance with

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RH-409.b., each licensee <u>previously or currently</u> authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

- 1. Records of disposal of licensed material made under RH-1401., RH-1402., a previous RH-1403. that authorized certain burials^{11/}, RH-1404., RH-1405., RH-1408.; and
- 2. Records required by RH-1500.c.2.D.

RH-1502.

RH-601. Reporting Requirements.

e. a. Immediate report.

Each licensee or registrant shall notify the Department as soon as possible but not later than four (4) hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits. (Events may include fires, explosions, toxic gas releases, et cetera.)-

f. b. Twenty-four hour report.

Each licensee or registrant shall notify the Department within twenty-four (24) hours after the discovery of any of the following events involving licensed material:

- 1. An unplanned contamination event that:
 - A. Requires access to the contamination area, by workers or the public, to be restricted for more than twenty-four (24) hours by imposing additional radiological controls or by prohibiting entry into the area;
 - B. Involves a quantity of material greater than five (5) times the lowest annual limit on intake specified in Appendix G to Section 3 for the material; and
 - C. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than twenty-four (24) hours to decay prior to decontamination.

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- 2. An event in which equipment is disabled or fails to function as designed when:
 - A. The equipment is required by regulation or licensee condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
 - B. The equipment is required to be available and operable when it is disabled or fails to function; and
 - C. No redundant equipment is available and operable to perform the required safety function.
- 3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
- 4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
 - A. The quantity of material involved is greater than five (5) times the lowest annual limit on intake specified in Appendix G to Section 3 of these Regulations for the material; and
 - B. The damage affects the integrity of the licensed material or its container.

g. c. Preparation and submission of reports.

1...

Reports made by licensees or registrants in response to the requirements of this section must be made as follows:

Licensees or registrants shall make reports required by RH-1502.a. and RH-1502.b. paragraphs a. and b. of this section by telephone to the Department at 1-800-633-1735. To the extent that the information is available at the time of notification, the information provided in these reports must include:

- A. The caller's name, title, and call back telephone number;
- B. A description of the event, including date and time;
- C. The exact location of the event;
- D. The isotopes, quantities, and chemical and physical form of the licensed material involved; and

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E. Any personnel radiation exposure data available.

2. Written report.

Each licensee or registrant who that makes a report required by RH 1502.a. and RH-1502.b. paragraph a. or b. of this Ssection shall submit a written follow-up report within thirty (30) (thirty) days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Arkansas Department of Health. Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867. The reports must include the following:

A. Complete information required by paragraph c.1. of this section.

A. <u>B.</u> A description of the event, including t <u>The probable cause of the</u> event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

B. The exact location of the event;

C. The isotopes, quantities and chemical and physical form of the licensed material involved;

D. Date and time of the event;

- E. C. Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments; and
- F. D. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

RH-604 2. Inspections.

- a. Each licensee shall afford to the Department at all reasonable times opportunity to inspect radioactive material and the premises and facilities wherein such radioactive material is used or stored.
- b. Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by the licensee pursuant to these Regulations.

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RH-602 3. Tests.

Upon instruction from the Department, each licensee shall perform or cause to have performed and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary, including, but not limited to, tests of:

- a. <u>Sources of radiation radioactive material;</u>
- b. Facilities wherein radioactive materials are used or stored;
- c. Radiation detection and monitoring instruments; and
- d. Other equipment and devices used in connection with utilization or storage of licensed material.

RH-603 4.- RH-699. Reserved.

FOOTNOTES TO SECTION 2

<u>6</u>/

Attention is directed particularly to the provisions of Section 3 of these Regulations which relate to the labeling of containers. Deleted.

SECTION 3. STANDARDS FOR PROTECTION AGAINST RADIATION

PART A. GENERAL

RH-1003. Communications.

Except where otherwise specified, all communications concerning these Regulations may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

PART B. DEFINITIONS

RULES AND REGULATIONS FOR CONTROL OF SOURCES OF IONIZING RADIATION DRAFT OF CHANGES January 2017 Regulation Package

RH-1100. Definitions.

Act - The Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.), as amended. Act 8 of Second Extraordinary Session of 1961, as amended.

Licensed material - Source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general <u>license provided by</u> regulation or <u>a</u> specific license issued by the Department.

PART C. PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS

RH-1212. Leak Tests. Testing for Leakage and/or Contamination of Sealed Sources.

- a. Each sealed radioactive source possessed under the provisions of a specific license, other than hydrogen-3 (tritium), with a half-life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination prior to initial use and at intervals specified by the license. If there is reason to suspect that a sealed source might have been damaged, it shall be tested for leakage before further use.
- b. Leak tests shall be capable of detecting the presence of 0.005 microcurie of removable contamination. Any test conducted pursuant to RH 1212, which reveals the presence of 0.005 microcurie or more of removable contamination shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with RH-501.
- e. Within five (5) days after obtaining results of the test, the licensee shall file a report with the Department describing the equipment involved, the test results, and the corrective action taken.
- d. Where sealed sources are permanently mounted in devices or equipment, tests for contamination and leakage may be made by wiping appropriate accessible surfaces and measuring these wipes for transferred contamination. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Department.
- a. <u>A licensee possessing any sealed radioactive source under the provisions of a</u> specific license, except as specified in paragraph b, of this section, shall assure that:
 - 1. Each sealed source is tested for leakage and/or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed

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source was tested within the interval listed in the Sealed Source and Device Registry prior to transfer to the licensee:

- 2. Each sealed source that is not designed to emit alpha particles is tested for leakage and/or contamination at intervals not to exceed those listed in the Sealed Source and Device Registry:
- 3. Each sealed source that is designed to emit alpha particles is tested for leakage and/or contamination at intervals not to exceed three (3) months.
- 4. Each sealed source for which there is reason to suspect might have been damaged or might be leaking is tested for leakage and/or contamination before further use.
- 5. Tests for leakage and/or contamination shall be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample.
- 6. Test samples shall be collected at the most accessible area where contamination would accumulate if the sealed source were leaking.
- b. A licensee need not perform tests for leakage and/or contamination on the following sources:
 - 1. Sealed sources containing only radioactive material with a half-life of less than 30 days:
 - 2. Sealed sources containing only radioactive material as a gas:
 - 3. Sealed sources containing 100 microcuries (3.7 MBq) or less of beta- and/or photon-emitting material or 10 microcuries (370 kBq) or less of alphaemitting material:
 - 4. Sealed sources containing only hydrogen-3:
 - 5. Seeds of iridium-192 encased in nylon ribbon: and
 - 6. Sealed sources, except for alpha sources, which are stored, not being used and are identified as being in storage. The licensee shall, however, test each such sealed source for leakage and/or contamination and receive the test results before any use or transfer unless it has been tested for leakage and/or contamination within the required leak test interval before the date of use or transfer. No sealed source shall be stored for a period of more than 3 years without being tested for leakage and/or contamination.

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- c. Tests for leakage and/or contamination, including sample collection and analysis, shall be performed by persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such services.
- d. Records of test results for leakage and/or contamination shall be made in accordance with RH-1500.j.
- e. Any test conducted pursuant to RH-1212, which reveals the presence of 0.005 microcuries (185 Bq) or more of removable contamination shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with these Regulations.
- f. Reports of test results indicating a leaking sealed source shall be made to the Department in accordance with RH-1508.

PART D. PRECAUTIONARY PROCEDURES

RH-1303. Caution Signs, Labels, and Signals....

5.

- b. Posting requirements. ...
 - 4. Posting of Airborne Radioactivity Area.

The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored.

The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding ten (10) times the quantity of such material specified in Appendix H to Section 3 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

RH-1310. Exemptions to Labeling Requirements.

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A licensee is not required to label:

a. Containers holding licensed material in quantities less than the quantities listed in Appendix H to Section 3 entitled "Quantities of Licensed or Registered Material Requiring Labeling"; or

PART F. RECORDS, REPORTS, NOTIFICATIONS, AND TESTS

RH-1500. Records.

a. General provisions.

- 1. Each licensee or registrant shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Section.
- In the records required by this Section, the licensee may record quantities in the International System of Units (SI) units in parentheses following each of the units specified in RH-1500. paragraph a.1. of this section. However, all quantities must be recorded as stated in RH-1500. paragraph a.1. of this section.
- Notwithstanding the requirements of RH-1500. paragraph a.1. of this section, when recording information on shipment manifests, as required in RH-1406.b., information must be recorded in the International System of Units (SI) or; in SI and units as specified in RH-1500. paragraph a.1. of this Section.
- 4. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Section (e.g., total effective dose equivalent, shallow-dose equivalent, eye lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

b. Records of radiation protection programs.

- 1. Each licensee or registrant shall maintain records of the radiation protection program, including:
 - A. The provisions of the program; and
 - B. Audits and other reviews of program content and implementation.

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2. The licensee or registrant shall retain the records required by RH 1500. paragraph b.1.A. of this section until the Department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by RH 1500.paragraph b.1.B. of this section for three (3) years after the record is made.

RH-1500. (Cont'd)

c. Records of surveys.

- 1. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by RH-1300. and RH-1307. The licensee or registrant shall retain these records for three (3) years after the record is made.
- 2. The licensee or registrant shall retain each of the following records until the Department terminates each pertinent license or registration requiring the record:
 - A. Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;
 - B. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;
 - C. Records showing the results of air sampling, surveys, and bioassays required pursuant to RH-1303.f.5.A.iii.; and
 - D. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

d. Determination of prior occupational dose.

- 1. For each individual who may enter the licensee's or registrant's restricted or controlled area and is likely to receive, in a year, an <u>annual</u> occupational dose requiring monitoring pursuant to RH-1302., the licensee <u>or registrant</u> shall:
 - A. Ddetermine the occupational radiation dose received during the current year; and
 - B. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

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- 2. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:
 - A. The internal and external doses from all previous planned special exposures; and
 - B. All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.
- 3. In complying with the requirements of <u>paragraphs d.1.and d.2.</u> RH-1500.d.1. of this section, a licensee or registrant may:
 - A. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;
 - B. Accept, as the record of lifetime cumulative radiation dose, an upto-date Department Form Z (Appendix L to Section 3) RC FORM <u>111</u>, or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and
 - C. Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant) by telephone, telegram, electronic media, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

RH-1500.d. (Cont'd)

4. The licensee or registrant shall record the exposure history, as required by paragraphs d.1. and d.2. RH 1500.d.1. of this section, on Department Form Z (Appendix L to Section 3) an up-to-date RC FORM 111, or other clear and legible record, of including all of the information required on that form ^{6/}. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or

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registrant shall use the dose shown in the report in preparing Department Form Z RC FORM 111, or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Department Form Z RC FORM 111, or equivalent, indicating the periods of time for which data are not available.

- 5. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:
 - A. In establishing administrative controls under RH-1200.f. for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
 - B. That the individual is not available for planned special exposures.
- 6. The licensee or registrant shall retain the records on Department Form Z (Appendix L to Section 3) <u>RC FORM 111</u>, or equivalent, until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Department Form Z <u>RC FORM 111</u>, or equivalent, for three (3) years after the record is made.

e. Records of planned special exposures.

For each use of the provisions of RH-1205. for planned special exposures, the licensee or registrant shall maintain records that describe:

A. The exceptional circumstances requiring the use of a planned special exposure:

RH-1500.e. (Cont'd)

L.

- B. The name of the management official who authorized the planned special exposure and a copy of the signed authorization;
- C. What actions were necessary;
- D. Why the actions were necessary;
- E. How doses were maintained ALARA; and
- F. What individual and collective doses were expected to result and the doses actually received in the planned special exposure.

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2. The licensee or registrant shall retain the records until the Department terminates each pertinent license or registration requiring these records.

f. Records of individual monitoring results.

1. Recordkeeping requirement.

Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RH-1302., and records of doses received during planned special exposures, accidents, and emergency conditions. These records^{I/I} must include, when applicable:</sup>

- A. The deep-dose equivalent to the whole body, eye <u>lens</u> dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;
- B. The estimated intake of radionuclides (See RH-1201.);
- C. The committed effective dose equivalent assigned to the intake or body burden of radionuclides;
- D. The specific information used to calculate the committed effective dose equivalent pursuant to RH-1203.a. and RH-1203.c. and when required by RH-1302.;
- E. The total effective dose equivalent when required by RH-1201.; and

RH-1500.f.1. (Cont'd)

- F. The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.
- 2. Recordkeeping frequency.

The licensee or registrant shall make entries of the records specified in $\frac{RH}{1500.paragraph}$ f.1. of this section at least annually.

3. **Recordkeeping format.**

The licensee or registrant shall maintain the records specified in RH-1500. <u>paragraph</u> f.1. of this section on Department Form Y (Appendix I to Section 3) an up-to-date RC FORM 110, in accordance with the instructions for Department Form Y <u>RC FORM 110</u>, or in clear and legible records containing all the information required by that form.

4. **Privacy protection**.

The records required under this section should be protected from public disclosure because of their personal privacy nature.

- 5. The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy including the estimated date of conception, shall also be kept on file but may be maintained separately from the dose records.
- 6. The licensee or registrant shall retain each required form or record until the Department terminates each pertinent license or registration requiring the record.

g. Records of dose to individual members of the public.

- 1. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (See RH-1208.).
- 2. The licensee or registrant shall retain the records required by RH-1500. paragraph g.1. of this section until the Department terminates each pertinent license or registration requiring the record.

RH-1500. (Cont'd)

h. Records of waste disposal.

- Each licensee or registrant shall maintain records of the disposal of licensed materials made under RH-1401., RH-1402., a previous RH-1403. that authorized certain burials^{8/}, RH-1404., RH-1405., and RH-1408.
- 2. The licensee or registrant shall retain the records required by paragraph h.1. of this section until the Department terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination, are located in RH-600.
- i. Records of testing entry control devices for very high radiation areas.
 - 1. Each licensee or registrant shall maintain records of tests made under RH-1303.e.1.I. on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

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- 2. The licensee or registrant shall retain the records required by RH-1500. paragraph i.1. of this section for three (3) years after the record is made.
- j. Form of records.

Each record required by this Section must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

Records of tests for leakage and/or contamination of sealed sources.

- Each licensee shall maintain records of tests for leakage and/or contamination of sealed sources required by RH-1212.a. These records must include identification of the source such as manufacturer, model number, and serial number: the date the sample was collected: the date the sample was analyzed; and the measured activity of the sample in units of microcuries or becquerels.
- 2. The licensee shall retain the records required by paragraph j.1. of this section for three (3) years after the record is made.

RH-1512. k. Records Rrequired at Ttemporary Jjobsites.

- **a.** Each licensee or registrant conducting activities as described in the definition for temporary jobsite in RH-1100. shall have the following records available at the temporary jobsite for inspection by the Department:
 - 1. Current copy of appropriate license issued by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.
 - 2. A copy of these Regulations.
 - 3. Operating and Emergency Procedures.
 - 4. The latest instrument calibration, if applicable.
 - 5. Survey records required pursuant to RH-1803.c. for the period of operation at the jobsite, if applicable.

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- 6. The latest leak test record for the device(s) in use at the jobsite.
- 7. Daily pocket dosimeter record for the period of operation at the jobsite, if applicable.
- I. Reserved.
- m. Reserved.

n. 1. Record retention periods.

- A. Each licensee or registrant shall retain each record that is required by this Section or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Department terminates each license or registration that authorizes the activity that is subject to the record keeping requirement.
- B. If there is a conflict between the Department's regulations in this Section, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this Section for such records shall apply unless the Department, pursuant to RH-2000, has granted a specific exemption from the record retention requirements specified in the regulations in this Section.

Form of records 2. Record maintenance.

Each record required by this Section must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

RH-1501. Reports of Theft or Loss of Lost, Stolen, or Missing Licensed or Registered Sources of Radiation.

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Each licensee or registrant shall report promptly by telephone and confirm promptly by letter to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205 3867, the theft or loss as soon as such theft or loss becomes known to the licensee or registrant of:

a.--- Any radiation machine; or

b. Any quantity of radioactive material in excess of a quantity generally licensed under RH 900., Schedule A or RH-901., Schedule B, in Section 2 of these Regulations.

e. a. Telephone reports.

- 1. Each licensee or registrant shall report to the Department by telephone as follows:
 - A. Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix H to Section 3 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or
 - **B.** Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than ten (10) times the quantity specified in Appendix H to Section 3 that is still missing at this time.
 - C. Immediately after its occurrence becomes known to the registrant, a lost, stolen, or missing radiation machine.
- 2. Reports must be made as follows:

All licensees or registrants shall make reports to the Department at 1-800-633-1735.

d. b. Written reports.

- 1. Each licensee <u>or registrant</u> required to make a report under RH-1501. <u>paragraph a.</u> of this section shall, within 30 days after making the telephone report, make a written report <u>to the Department</u> setting forth the following information:
 - A. A description of the licensed material or registered source of radiation involved, including, for radioactive material, kind, quantity, and chemical and physical form; and, for radiation

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machines, the manufacturer, model number, serial number, and type and maximum energy of radiation emitted:

- B. A description of the circumstances under which the loss or theft occurred;
- C. A statement of disposition, or probable disposition, of the licensed material or registered source of radiation involved;
- D. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
- E. Actions that have been taken, or will be taken, to recover the material source of radiation; and
- F. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material <u>or</u> registered sources of radiation.
- 2. Reports must be made as follows:
 - A. All licensees or registrants shall make reports to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.
 - **B.** Subsequent to filing the written report, the licensee or registrant shall also report any additional substantive information on the loss or theft within <u>thirty (30)</u> days after the licensee or registrant learns of such information.
- C: The licensee or registrant shall prepare any report filed with the Department pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

RH-1502. Notification of Incidents.

<u>c.</u>

a. Immediate notification.

Notwithstanding any other requirements for notification, eEach licensee or registrant shall immediately notify the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867, by telephone and confirming letter of any incident report to the Department any event involving any source of radiation possessed by the licensee
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or registrant and which that may have caused or threatens to cause any of the following conditions:

- 1. An individual to receive:
 - A. A total effective dose equivalent of 25 rems (0.25 Sv) or more; or
 - B. A lens dose equivalent of 75 rems (0.75 Sv) or more; or
 - C. A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or
- 2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual could have received an intake five (5) times the occupational annual limit on intake. (The provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.).

b. **Twenty-four hour notification**.

Each licensee or registrant shall, within twenty-four (24) hours of discovery of the event, notify the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867, by telephone and confirming letter of any incident report to the Department any event involving loss of control of any licensed or registered source of radiation possessed by the licensee or registrant and which that may have caused, or threatens to cause, any of the following conditions:

- 1. An individual to receive, in a period of twenty-four (24) hours:
 - A. A total effective dose equivalent exceeding five (5) rems (0.05 Sv); or
 - B. A lens dose equivalent exceeding fifteen (15) rems (0.15 Sv); or

RH-1502.b.1. (Cont'd)

- C. A shallow-dose equivalent to the skin or extremities exceeding fifty (50) rems (0.5 Sv); or
- 2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual could have received an intake in excess of one occupational annual limit on intake. (The provisions of this paragraph do not apply to

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locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.).

- c. Licensees or registrants shall make the reports required by this section by telephone to the Department at 1-800-633-1735 and by confirming letter to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.
- e. <u>d.</u> The licensee or registrant shall prepare any report filed with the Department pursuant to this section so that names of individuals who have received exposure to sources of radiation or radioactive material are stated in a separate and detachable part of the report.
- d. e. The provisions of this section do not include doses that result from planned special exposures, that provided such doses are within the limits for planned special exposures, and that are reported under RH-1504 1503.

e. Immediate report.

Each licensee or registrant shall notify the Department as soon as possible but not later than four (4) hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (Events may include fires, explosions, toxic gas releases, et-cetera.).

f. Twenty-four hour report.

Each licensee or registrant shall notify the Department within twenty-four (24) hours after the discovery of any of the following events involving licensed material:

---- An unplanned contamination event that:

- A. Requires access to the contamination area, by workers or the public, to be restricted for more than twenty-four (24) hours by imposing additional radiological controls or by prohibiting entry into the area;
- B. Involves a quantity of material-greater than five (5) times the lowest annual limit on intake specified in Appendix G to Section 3 for the material; and
- C. Has access to the area restricted for a reason other than to allow isotopes with a half life of less than twenty-four (24) hours to decay prior to decontamination.

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- 2. An event in which equipment is disabled or fails to function as designed when:
 - A. The equipment is required by regulation or licensee condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
 - B. The equipment is required to be available and operable when it is disabled or fails to function; and
 - C. No redundant equipment is available and operable to perform the required safety function.
- 3: An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
- 4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
 - A: The quantity of material involved is greater than five (5) times the lowest annual limit on intake specified in Appendix G to Section 3 of these Regulations for the material; and
 - B. The damage affects the integrity of the licensed material or its container.

g. Preparation and submission of reports.

Reports made by licensees or registrants in response to the requirements of this section must be made as follows:

Licensees or registrants shall make reports required by RH-1502.a. and RH-1502.b. by telephone to the Department at 1-800-633-1735. To the extent that the information is available at the time of notification, the information provided in these reports must include:

- A. The caller's name and call back telephone number;
- B. --- A description of the event, including date and time;
- C. The exact location of the event;
- D. The isotopes, quantities, and chemical and physical form of the licensed material involved; and

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E. Any personnel radiation exposure data available.

3. Written report.

Each licensee or registrant who makes a report required by RH-1502.a. and RH-1502.b. of this Section shall submit a written follow-up report within 30 (thirty) days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

The reports must include the following:

A. A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned:

B. The exact location of the event;

- C. The isotopes, quantities and chemical and physical form of the licensed material involved;
- D. Date and time of the event;
- E. Corrective actions taken or planned and the results of any evaluations or assessments; and
- -- The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

RH-1503. Tests.

Each licensee and registrant shall perform upon instructions from the Department, or shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary including, but not limited to, tests of:

a.- Sources of radiation;

b. Facilities wherein sources of radiation are used or stored;

c. Radiation detection and monitoring instruments; and

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d. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

Reports of Planned Special Exposures.

The licensee or registrant shall submit a written report to the Department within thirty (30) days following any planned special exposure conducted in accordance with RH-1205, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by RH-1500,e.

RH-1504. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.

a. **Reportable events.**

In addition to the notification required by RH-1502., each licensee or registrant shall submit a written report within <u>thirty (30)</u> days after learning of any of the following occurrences:

- 1. Any incident for which notification is required by RH-1502.; or
- 2. Doses in excess of any of the following:
 - A. The occupational dose limits for adults in RH-1200.; or
 - B. The occupational dose limits for a minor in RH-1206.; or
 - C. The limits for an embryo/fetus of a declared pregnant woman in RH-1207.; or
 - D. The limits for an individual member of the public in RH-1208.; or
 - E. Any applicable limit in the license; or
 - The ALARA constraints for air emissions established under RH-1004.d.
- 3. Levels of radiation or concentrations of radioactive material in:
 - A. A restricted area in excess of any applicable limit in the license; or
 - B. An unrestricted area in excess of ten (10) times any applicable limit set forth in this Section or in the license (whether or not involving exposure of any individual in excess of the limits in RH-1208.); or

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4. For licensees subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

b. Contents of reports.

- 1. Each report required by RH-1504.a. paragraph a. of this section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:
 - A. Estimates of each individual's dose;
 - B. The levels of radiation and concentrations of radioactive material involved;
 - C. The cause of the elevated exposures, dose rates, or concentrations; and

RH-1504.b.1. (Cont'd)

- D. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.
- 2. Each report filed pursuant to RH-1504.a. paragraph a. of this section must include for each occupationally overexposed⁹ individual: the name, social security number, or other unique identifier, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report.
- 3. The licensee or registrant shall prepare any report filed with the Department pursuant to this section so that names of individuals who may have received exposure to sources of radiation are stated in a separate and detachable part of the report.
- c. Licensees or registrants who make reports pursuant to paragraph a. of this section shall submit the report in writing to the Arkansas Department of Health Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-1505. Notifications and Reports to Individuals.

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a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Part N of this Section (RH-2804).

b. Reports to individuals of exceeding dose limits.

When a licensee or registrant is required, pursuant to the provisions of <u>RH-1503</u>. or RH-1504., <u>RH-1505.b.</u>, or <u>RH-1509</u>., to report to the Department any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, <u>the licensee or registrant shall also</u> provide the individual a report on his or her exposure data included in the report to the Department. The report must be transmitted no later than the transmittal to the Department.

RH-1506. Notification of Intent to Vacatinge Premises.

Each specific licensee shall, no less than thirty (30) days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's activities, notify the Department in writing of intent to vacate. When deemed necessary by the Department, the licensee shall decontaminate the premises in such a manner as the Department may specify.

RH-1507. Deleted. Refer to RH-8703. and RH-8800.

RH-1508. Deleted.

Reports of Leaking Sealed Sources.

A licensee shall file a report with the Department within five (5) days if a test for leakage and/or contamination required by RH-1212. reveals the presence of 0.005 microcuries (185 Bq) or more of removable contamination. The written report must include the results of the test: the date the test results were received: identification of the source such as manufacturer, model number, and serial number: the radionuclide and its estimated activity: any equipment involved; any contamination which resulted from the leaking source; and the corrective actions taken.

RH-1509. Reports of Individual Monitoring.

- a. This section applies to each person licensed by the Department to:
 - 1. Possess or use radioactive material for purposes of radiography pursuant to Part I of Section 3; or

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2. Possess or use at any time, for processing or manufacturing for distribution pursuant to Section 2 or 9 of these Regulations, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Quantity of Radionue Activity	
	Ci	GBq
Cesium-137	1	<u>37</u>
Cobalt-60		<u>37</u>
Gold-198	100	<u>3,700</u>
Iodine-131	1	<u>37</u>
Iridium-192	10	<u>370</u>
Krypton-85	1,000	37,000
Promethium-147	10	<u>370</u>
Technetium-99m	1,000	<u>37.000</u>

TABLE TO RH-1509.a.2.

- ^a The Department may require as a license condition, or by rule, Regulation, or order pursuant to RH-2001., reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.
- b. Each licensee in a category listed in RH-1509.a. paragraph a. of this section shall complete an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by RH-1302. during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use Department Form Y (Appendix I to Section 3) an up-to-date RC FORM 110 or electronic media equivalent containing all the information required by Department Form Y RC FORM 110.

RH-1509 (Cont'd)

c. The licensee shall complete the report required by RH-1509.b. paragraph b. of this section, covering the preceding year, on or before May 31 of each year. The licensee shall retain the report and submit it, if requested, to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-1510. Deleted. Refer to RH-8308., RH-8703., and RH-8800.

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RH-1511. Deliberate Misconduct.

- a. Any licensee, registrant, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee or registrant, certificate of registration holder, or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee, registrant, or certificate of registration holder, or applicant for a license, registration, or certificate of registration, who knowingly provides to any licensee, registrant, applicant, certificate holder, contractor or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's, certificate holder's, or applicant's activities subject to this Section may not:
 - 1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Department; or
 - 2. Deliberately submit to the Department, a licensee, registrant, certificate of registration holder, an applicant, or a licensee's, registrant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.
- b. A person who violates RH 1511.a.1. or 2. of this section may be subject to enforcement action in accordance with the procedures in RH-2110.
 - For purposes of RH 1511.a.1., deliberate misconduct by a person means an intentional act or omission that the person knows:
 - 1. -Would cause a licensee, registrant, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Department; or
 - 2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order or policy of a licensee, registrant, certificate of registration holder, applicant, contractor, or subcontractor.

Deleted. Refer to RH-107.

RH-1512. Deleted. Refer to RH-1500.k.

Records Required at Temporary Jobsites.

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- a. Each licensee or registrant conducting activities as described in the definition for temporary jobsite in RH 1100. shall have the following records available at the temporary jobsite for inspection by the Department:
 - 1. Current copy of appropriate license issued by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.
 - 2. A copy of these Regulations.
 - 3. Operating and Emergency Procedures.
 - 4. The latest instrument calibration, if applicable.
 - 5. Survey records required pursuant to RH-1803.c. for the period of operation at the jobsite, if applicable.
 - 6. The latest leak test record for the device(s) in use at the jobsite.
 - 7. Daily pocket dosimeter record for the period of operation at the jobsite, if applicable.

RH-1513. Reports of Transactions Involving Nationally Tracked Sources.

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in RH-1513.paragraphs a. through e. of this section for each type of transaction. See Appendix D to Section 3, "Nationally Tracked Source Thresholds." ...

- f. The reports discussed in RH 1513. paragraphs a. through RH 1513.e. of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using: ...
- g. Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five (5) business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by RH 1513. paragraphs a. through RH-

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<u>1513.e. of this section.</u> By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

RH-1514. RH-1599 19. Reserved.

RH-1503.

RH-1520. Tests.

Upon instruction from the Department, <u>Ee</u>ach licensee and registrant shall perform upon instructions from the Department or cause to have performed, or and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary, including, but not limited to, tests of:

- a. Sources of radiation;
- b. Facilities wherein sources of radiation are used or stored;
- c. Radiation detection and monitoring instruments; and
- d. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

RH-1521.- RH-1599. Reserved.

PART I.

LICENSES FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

- RH-1800. General Provisions.
 - c. Definitions.

Radiographer instructor—A radiographer who instructs and supervises radiographer's assistants during on-the-job training and who meets the requirements of RH-1803.f.5.

- RH-1801. Equipment Control. ...
 - f. Leak testing and replacement of sealed sources. ...

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3. Testing and recordkeeping requirements.

A. Each licensee who uses a sealed source shall have the source tested for leakage in accordance with RH-1212. and as prescribed in this Part. Tests for leakage must be performed at intervals not to exceed six (6) months. The leak testing of the source must be performed using a method approved by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department, or designee, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform the analysis.

k. Notifications.

- In addition to the reporting requirements specified in RH-1502 601. and under other Sections, each licensee or registrant shall provide a written report to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867 within thirty (30) days of the occurrence of any of the following incidents involving radiographic equipment:
 - A. Unintentional disconnection of the source assembly from the control cable. ...

RH-1802. Personnel Radiation Safety Requirements for Radiographers and Radiographer's Assistants. ...

b. **Training**.

- 1. The licensee or registrant may not permit any individual to act as a radiographer until the individual has received training in RH-1804... in addition to a minimum of two (2) months of on-the-job training under the supervision of a radiographer, and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Schedule B to Section 3.
- 2. In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

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- A. Has received copies of and instructions in the requirements described in this Part; RH-1511. 107.; in the applicable sections of Section 3, "Standards for Protection Against Radiation," (including its Part N, "Notices, Instructions, and Reports to Workers; Inspections"); in applicable Department of Transportation (DOT) regulations as referenced in Section 4 of these Regulations and the Nuclear Regulatory Commission's (NRC) 10 CFR Part 71; in the Department license(s) under which the radiographer will perform industrial radiography; and the licensee's or registrant's operating and emergency procedures; ...
- 3. The licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:
 - A. Has received copies of and instructions in the requirements described in this Part; RH-1511. 107.; in the applicable sections of Section 3, "Standards for Protection Against Radiation," (including its Part N, "Notices, Instructions, and Reports to Workers; Inspections"); in applicable Department of Transportation (DOT) regulations as referenced in Section 4 of these Regulations and the Nuclear Regulatory Commission's (NRC) 10 CFR Part 71; in the Department license(s) under which the radiographer's assistant will perform industrial radiography; and the licensee's or registrant's operating and emergency procedures; ...

c. Radiographer certificate card confiscation.

The Department may confiscate any radiographer's certification card should there be serious health and safety violations relating to the Regulations, license conditions, and/or licensee operating and emergency procedures. The radiographer will be restricted from conducting radiographic operations within the State of Arkansas.

1. Following the confiscation of the radiographer's certification card, the conduct of any radiographic operations by this radiographer within the State of Arkansas shall be deemed deliberate misconduct as detailed in RH-1511 107....

g. Reciprocity of a radiographer certification.

- 1. Reciprocal recognition by the Department of an individual radiographer certification will be granted provided that:
 - A. The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in RH-1800.c.:

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- B. The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by RH-1802.b.1.; and
- C. The individual presents the certification to the Department prior to entry into the State.
- 2. The Department may withdraw, limit, or qualify its acceptance of any individual radiographer certification based on enforcement actions with the Department, another Agreement State, or the Nuclear Regulatory Commission or sanctions by an independent certifying entity in order to prevent undue hazard to public health and safety or property.
- 3. Certified individuals who are granted reciprocity by the Department shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of RH-1802.b.1.
- RH-1803. Precautionary Procedures in Radiographic Operations. ...
 - f. Specific requirements for radiographic personnel performing industrial radiography.
 - 1. At a job site, the following shall be supplied by the licensee or registrant:
 - A. At least one operable, calibrated survey instrument;
 - B. A current whole body personnel dosimeter monitor (i.e., TLD, film badge, or Optically Stimulated Dosimeter) that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor for each individual performing radiographic operations;
 - C. An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each worker individual performing radiographic operations; and
 - D. An operable, calibrated alarming ratemeter set to give an alarm signal at a preset dose rate of 500 mR/hr for each individual performing radiographic operations; and
 - E. The appropriate barrier ropes and signs.
 - 2. Each radio rapher shall have available at the job site a valid certification ID card issued by a certifying entity.

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- 2 <u>3</u>. Industrial radiographic operations shall not be performed if any of the items in RH-1803.f.1. paragraphs f.1. and f.2. of this section are not available at the job site or are inoperable.
- 3. No individual other than a radiographer or a radiographer's assistant who is under the personal supervision of a radiographer instructor shall manipulate controls or operate equipment used in industrial radiographic operations.
- 4. During an inspection by the Department, the Department inspector may terminate an operation if any of the items in RH-1803.f.1. paragraphs f.1. and f.2. of this section are not available and operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.
- 5. No individual shall act as a radiographer instructor unless such individual:
 - A. Has met the requirements of RH 1802.b.1.;
 - B. Has one year of documented experience as an radiographer; and
 - C. Has been named as a radiographer instructor on the license or registration certificate issued by the Department.

PART J.

LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

RH-1935. Leak **#Testing of sSealed sSources**.

a. Testing and recordkeeping requirements.

Each licensee who uses a sealed source shall have the source leak tested for leakage periodically in accordance with RH-1212. and as prescribed in this section. The licensee shall keep a record of leak test results in units of microcuries and retain the record for inspection by the Department for three (3) years after the leak test is performed.

RH-1977. Notification of Incidents and Lost Sources; Abandonment Procedures for Irretrievable Sources. ...

b. The licensee shall notify the Department of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation,

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and certain other accidents as required by <u>RH-601.</u>, RH-1501., RH-1502., and RH-1504. of these Regulations.

PART N.

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

RH-2801. **Purpose and Scope**.

This Part establishes requirements for notices, instructions, and reports by licensees or registrants to individuals engaged in work under a license or registration; and options available to such individuals in connection with Department inspection of licensees or registrants to ascertain compliance with the provisions of the Act and the regulations, orders, and licenses issued thereunder regarding radiological working conditions. The Regulations in this Part apply to all persons who receive, possess, use, own, or transfer sources of radiation licensed by or registered with the Department pursuant to these Regulations in <u>Section 1 and Section 2</u> Sections 1 and 2, Part I to Section 3, Part J to Section 3, and Sections 6, 7, 8, and 9.

RH-2804. Notifications and Reports to Individuals. ...

f. When a licensee or registrant is required pursuant to RH-1502.<u>RH-1503.</u> or RH-1504. to report to the Department any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his or her exposure data included in the report to the Department. The report must be transmitted no later than the transmittal to the Department.

RH-2808. Inspections Not Warranted; Informal Review.

- a. If the Department determines, with respect to a complaint under RH-2807., that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Department shall notify the complainant in writing of such determination.
 - 1. The complainant may obtain review of such determination by submitting a written statement of position to the Director who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant.

(NOTE: As shown below, Department Form Y, "Occupational Exposure Record for a Monitoring Period," and Form Z, "Cumulative Occupational Exposure History," are being removed from the regulations. Current revisions will be available on the ADH website. Form Y (soon to be RC FORM 110), or its equivalent, and Form Z (soon to be RC FORM 111), or its equivalent, are referenced in RH-1500. and RH-1509.)

OCCUPA	THONAL	OCCUPATIONAL EXPOSURE	T	RECORD FOR A MONITORING PERIOD			-
1 Name: Last, First, Middle Initial	t , Fi rst, Midd	le Initial		2. Identification Name 3. ID Type 4.	4. Sex. 5. D MorF	5. Date of Birth	1
6. Monitoring Period	Period	7. Licensee	7. Licensee or Registrant Name	8. Licensee of Registration Number	9 B. Record o	+	9B. Routine or
	*	INTAKES			1721		ŧ.
<u>+10A.</u> Radionuclide	10B. Class	10C. Mode	10D. Intake in µCi	DOSES (in rem)			
				Deep Dose Equivalent (DDE)	4		
				Eye Dose-Equivalent to the lens of the eye (LDE)	4		
				Shallow Dose Equivalent, Whole Body (SDE, WB)	13.		
				Shallow Dose Equivalent, Max Extremity (SDE, ME)	4		
				Committed Effective Dose Equivalent (CEDE)	15.		
				Committed Dose Equivalent, Maximally Exposed Organ (CDE)	16.		
				TOTAL EFFECTIVE DOSE EQUIVALENT (TEDE) (Blocks 11 & 15)	17		
			1	TOTAL ORGAN DOSE EQUIVALENT, MAX ORGAN (TODE) (Blocks 11 & 16)	E) 18.		
		3		19. Comments			
20. Signature of Licensee or Registrant	of Licensee of	r Registrant			21. E	21. Date Prepared	ared

Appendix K to Section 3

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RKANSAS DEPARTMENT OF HEALTH NAL INFORMATION PERTINENT TO THE COMPLETION OF FORM Y	10.B. — Enter the lung clearance class as noted in Appendix (3 to Section 3 (1) W, Y, V, or O for other) for all intukes by inhalation.	10-C - Rater the mode of intake. For inhalation, enter "IL". For absorption through the skin, enter "IL" enter "L".	10.12Enter the marke of each radiomiclide in µCi.	11Enter the deep dose equivalent (DDB) to the whole body.	42. — - Enter the eye dose equivalent (LDE) recorded for the lens of the eye.	13Enter-the shallow dose equivalent recorded for the skin of the whole body (SDE, WB).	14	15. Enter the committed effective dose equivalent or "NR" for "Not Required" or "NC" for "Not Calmined."	16 Futer the committed dose equivalent (CDE) recorded for the maximally exposed organ or "NR" for "Not Required" or "NC" for "Not Calculated."	17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.	18. Eater the total organ dese equivalent (TODE) for the maximally exposed organ. The movie is the arrest is the source of items of the order of the source	+ULDE-15 the sum of them is a new residence of the person designated to represent the licensee or registrant.	20. — Enter the date this form was prepared.	21. In the space provided for comments, enter additional information that might be needed to determine compliance with limits. An example might be to enter the note that the SDE, ME was the result of exposure from a discrete, hot particle. Another possibility would be to indicate that an overexposure report has been sent to the Agency in reference to the exposure report.	<u>(All doses should be stated in rem.)</u>	Appendix K to Section 3
ARKANSAS DEPARTMENT OF HEALTH INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO TH	 Type or print the full name of the monitored minvidual in the order of last name (include Jr., Sr., III, etc.), first name, and midulle name (if applicable). 	2. — Enter the individual's identification number, including punctuation. This number sitened be the 9-digit social-security number or other-unique identifier.	3Enter the code for the type of identification used as follows	CODE	PPN Passport Number CSI Canachan Social Insurance Number	WPN — Work Permit Number IND — Index Identification Number	GTHCthee 4Cirole the sex of the individual being monitored.		6.— Enter the monitoring period for which this report is filed. The format alcould be MM/DD/YY — MM/DD/YY.	 Enter the name of the licensee or registrant. T_ten to A more lighted or registrant. 	9.4. Circle either Record or Estimate. Choose "Record" if the dose data lysted represent a final	determination of the dose received to the best of the li censee's or registrant's knowledge. Choose "Estimate" only if the listed dase data are prelimin ary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance	would be doze data based on self reading dosmeter results, and the licensee intends to assign the record doze on the basis of TLD results that are not yet avaidable.	9.B. Circle either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routime exposures. Choose "PSE" if the listed dose data represent the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the lecense or registrant should sum them and report the total of all PSE"s.	10.A. Futer the symbol for each radionuclide that resulted in an internal exponse recorded for the individual, using the format "Xx 41/1/1×" (for mistance, Cs-137 or To-99m).	Arkansas Department of Health

CUMULA	HVE OCCU	CUMULATIVE OCCUPATIONAL EXPOSURE HISTORY	POSURE HI	STORY			
I, Name: Last, J	1. Name: Last, First, Middle Initial	-+	2. Identification Name	Name	3. ID Type	4. Sex Mor F	5Date of Birth
6. Monitoring Period	stied	7. Licensee or Registrant Name	gistrant Name	8. License or Re	8. License or Registration Number	9. Record/ Estimate/ No. Pacord	<u>10. Routine or</u> PSE
H. DDE	<u>+2. LDE</u>	13. SDE, WB	14. SDE, ME	15, CEDE	<u>16. CDE</u>	17. TEDE	<u>18. TODE</u>
6. Monitoring Period	hind	7. Licensee or Registrant Name	gi strant Name	8. License or Rey	8. License or Registration Number	9. Record/ Estimate/ No_Record	<u>10. Routine or</u> PSE
II. DDE	12. []DE	13. SDE, WB	14. SDE, ME	t s. capt	16. CDE	17. TEDE	<u>18. TODE</u>
6. Monitoring Period	riod	7. Licensee or Registrant Name	gistrant Name	8. License or Rei	8. License or Registration Number	9. Record/ Estimate/ No Record	10. Routine or PSE
<u>11. DDE</u>	<u>12. LDE</u>	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	<u>18. TODE</u>
6. Monitoring Period	riod	7. Licensee or Registrant Name	gistrant Name	8. License or Reg	8. License or Registration Number	9. Record/ Estimate/ No Record	10. Routine of PSE
11. DDE	17. FDE	+3. SDE, WB	44. SDE, ME	ts. CEDE	16. CDE	17. TEDE	<u>18. TODE</u>
19. Signature of Monitored Individual	Monitored	20. Date Signed	21 - Certifying Organization	ganization	22. Signature of Designee	lesignee	23. Date Signed

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INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF FORM Z full name of the monitored individual in the order of last name (include 12 Enter the eye dose equivalent (LDE) recorded for the lens of the eye-	 Enter the shallow dose equivalent recorded for the skin of the whole budy (SDE, WB). 4Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maxmum dose (SDE, ME). 	 Enter the committed effective dose equivalent (CEDE). Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15. 	48. Ender the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16. 10. Signature of the monitored individual. The signature of the monitored individual on this form indicates that the information contained on the form is complete and correct to the	Rest-ot-line of the Knowtenge. 20. Enter the date this form was signed by the monitored individual. 21. (Optional) Enter the name of the heensee, registrant, or facility, not ficensed by the Agency providing monitoring for exposure to radiation (such as a DOE facility) or the employer if the individual is not employed by the licensee or registrant and the employer chooses to maintain exposure records for its employees.	 22 (Cptional) - Signature of the person designated to represent the licenses, registrant, or employer entered in item 21. The licensee, registrant, or employer entered in item 21. The licensee, registrant, or enumersup the form should have on-file documentation of all the information on the Agency Form Y being signed. 23 (Cptional) - Faster the date this form was signed by the designated representative. 	(All doses should be stated in rem.)	Appendix L to Section 3
INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO TH 1Type or print the full name of the monitored individual in the order of last name (include 12 Enter the eye-dove equi	Jr., Sr.; III, etc.), first-name, and muldle name (if applicable). 2. — Enter the individual's identification number, molnting punctuation. This number should be the 9-digit social security mumber or other unique identifier.		 CHHCliner Clinele the sex of the individual being monitored Enter the date of birth of the individual being monitored in the format MM/DD/YY. 	 Enter the monitoring period for which this report is filed. The format should be MM/DD/YY — MM/DD/YY. Enter the name of the licensee, registrant, or facility not licensed by the Ageney that provided monitoring. Enter the Ageney license or registration number or numbers. 	9. Circle either Record, Estimate, or No Record. Choose "Record" of the dose data listed represent a final determination of the dose received to the losit of the locenses "s or registrant's knowledge. Choose "Estimate" only if the listed dose data are preimmusty und will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data by a final determination resulting in a subsequent report. An example of such an instance would be dave data the record dose on the basis of TLD results that are not yet available.	 Circle either Routine or PSF. Cihoose "Routine" if the data represent the results of monitoring fix routine exposures. Choose "PSE" if the listed dose data represent the results of monitoring of planned special exposures received thring the monitoring period. If more than one PSE was received in a single year, the licensee or registrant should sum them and report the total of all PSE's. Eater the deep dose equivalent (DDE) to the whole body. 	Arkansas Department of Health

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FOOTNOTES TO SECTION 3

<u>6</u>/

Licensees are not required to reevaluate the separate partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s) or intakes of radionuclides assessed under RH 102. through RH-1308. Further, occupational exposure histories obtained and recorded on Department Form Z (Appendix L to Section 3) RC FORM 111 (formerly known as Department Form Z or Department Form RH-1), or equivalent, before January 1, 1994, would might not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

SECTION 4. TRANSPORTATION OF RADIOACTIVE MATERIALS

(FOOTNOTES APPEAR AT THE END OF THIS SECTION)

PART A. GENERAL

RH-3002. Purpose and Scope. ...

a. This Section establishes:

- **R**requirements for packaging, preparation for shipment, and transportation of licensed material; and
- 2. Procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of other licensed material in excess of a Type A quantity.
- b. The packaging and transport of licensed material are also subject to the regulations of other agencies (e.g., the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission, and the U.S. Postal Service) having jurisdiction over means of transport. The requirements of this Section are in addition to, and not in substitution for, other requirements.
- c. The regulations in this Section apply to any licensee authorized by specific or general license issued by the Department to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified

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in the Department license, or transports that material on public highways. No provision of this Section authorizes the possession of licensed material.

- d. 1. Exemptions from the requirement for license in RH-3004. are specified in RH-3202. General licenses for which no NRC package approval is required are issued in RH-3304. through RH-3306. The general license in RH-3301. requires that an NRC eCertificate of eCompliance or other package approval be issued for the package to be used under this general license.
 - 2. Application for package approval must be completed in accordance with U.S. Nuclear Regulatory Commission Regulations in Part 71, subpart D, "Application for Package Approval," demonstrating that the design of the package to be used satisfies the package approval standards contained in the U.S. Nuclear Regulatory Commission Regulations in Part 71, subpart E, "Package Approval Standards," as related to the tests of the U.S. Nuclear Regulatory Commission Regulations in Part 71, subpart F, "Package, Special Form, and LSA-III Tests."
 - 3.2. A licensee transporting licensed material, or delivering licensed material to a carrier for transport, shall comply with the operating control requirements of Part F; the quality assurance requirements of Part G; and the general provisions of Part A, including referenced U.S. DOT Department of Transportation regulations referenced in RH-3005.
- e. The regulations of this Section apply to any person holding, or applying for, a certificate of compliance, issued pursuant to this section, for a package intended for the transportation of radioactive material, outside the confines of a licensee's facility or authorized place of use.
- f. The regulations of this Section apply to any person required to obtain a certificate of compliance or an approved compliance plan pursuant to U.S. Nuclear Regulatory Commission Part 76 regulations if the person delivers radioactive material to a common or contract carrier for transport or transports the material outside the confines of the person's plant or other authorized place of use.
- g. This Section also gives notice to all persons who knowingly provide to any-licensee, certificate holder, quality assurance program approval or to a contractor, or subcontractor of any of them, components, equipment, materials, or other goods or services, that relate to a licensee's, certificate

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holder's, quality assurance program approval holder's or applicant's activities subject to this Section, that they may be individually subject to Department enforcement action for violation of RH 1511., "Deliberate Misconduct."

PART B. DEFINITIONS

RH-3100. **Definitions**.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

Certificate of Compliance (CoC) - the certificate issued by the <u>U.S.</u> Nuclear Regulatory Commission which approves the design of a package for the transportation of radioactive material.

Contamination - The presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm² ($1 \times 10^{-5} \mu \text{Ci/cm}^2$) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm² ($1 \times 10^{-6} \mu \text{Ci/cm}^2$) for all other alpha emitters.

- 1. Fixed contamination Contamination that cannot be removed from a surface during normal conditions of transport.
- 2. Non-fixed contamination Contamination that can be removed from a surface during normal conditions of transport.

Criticality Safety Index (CSI) - The dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks, or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in RH-3305., RH-3306., and in NRC Regulation § 10 CFR 71.59. The criticality safety index for an overpack, freight container, consignment, or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment, or conveyance.

Low Specific Activity (LSA) - Radioactive material with limited specific activity which is nonfissile or is excepted under RH-3203. and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. <u>The LSA material must be in one of three groups:</u>

- 1. LSA-I:
 - A. Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclides which that are not intended to be processed for the use of these radionuclides;
 - B. Solid unirradiated n Natural uranium, or depleted uranium, or natural thorium, or their solid or liquid compounds or mixtures, provided they are unirradiated and in solid or liquid form;
 - C. Radioactive material <u>other than fissile material</u> for which the A₂ value is unlimited; or
 - D. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with Appendix A to Section 4, "Determination of A₁ and A₂."

2. **LSA-II**:

- Water with tritium concentration up to 20.0 Ci/liter (0.8 TBq/liter) (20.0 Ci/liter); or
- B. <u>Other radioactive Mmaterial</u> in which the radioactive material activity is distributed throughout, and the estimated average specific activity does not exceed 10^{-4} A₂/g for solid and gases, and 10^{-5} A₂/g for liquids.

LSA-III:

3.

Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77, in which:

- A. The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and
- B. The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by

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leaching, when placed in water for seven (7) days, would will not exceed 0.1 A₂.; and

C. The estimated average specific activity of the solid, excluding any shielding material does not exceed $2 \times 10^{-3} A_2/g$.

Special form radioactive material - Radioactive material which that satisfies the following conditions:

- 1. It is either a single solid piece or is contained in a selected sealed capsule that can be opened only by destroying the capsule; and
- 2. The piece or capsule has at least one dimension not less than five (5) millimeters (0.2 inch); and
- 3. It satisfies the requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on June 30, 1983 (see 10 CFR Part 71, revised as of January 1, 1983), and constructed before July 1, 1985; and a special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on March 31, 1996 (see 10 CFR Part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was successfully tested before September 10, 2015 in accordance with the requirements of 10 CFR 71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

Indian tribe <u>Tribe</u> - An Indian or Alaska native tribe <u>Tribe</u>, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe <u>Tribe</u> pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

Uranium - natural, depleted, enriched.

- 1. **Natural uranium**--Uranium (which may be chemically separated) with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).
- 2. **Depleted uranium**. Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.
- 3. **Enriched uranium**-Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

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PART C. EXEMPTIONS

RH-3202. Exemption for Low-Level Radioactive Materials.

A licensee is exempt from all the requirements of this <u>sSection</u> with respect to shipment or carriage of the following low-level materials:

- a. Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed ten (10) times the applicable radionuclide activity concentration values specified in Table A-2 or Table A-3 of Appendix A to this Section <u>4</u>.
- b. Materials for which the activity concentration is not greater than the activity concentration values specified in Table A-2 or Table A-3 of Appendix A to this Section 4, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table A-2 or Table A-3 of Appendix A to this Section 4.
- c. Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in RH-3100.

RH-3203. Exemption from Classification as Fissile Material.

Fissile material meeting the requirements of at least one (1) of the paragraphs RH-3203.a. through f. of this section are exempt from classification as fissile material and from the fissile material package standards of U.S. Nuclear Regulatory Commission Regulations §§ 10 CFR 71.55 and 71.59, but are subject to all other requirements of this sciencies as noted. ...

d. Uranium enriched in uranium-235 to a maximum of one percent (1%) by weight, and with total plutonium and uranium-233 content of up to one percent (1%) of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five percent (5%) of the uranium mass<u>and that the fissile material is distributed homogenously and does not form a lattice arrangement within the package</u>.

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PART D. GENERAL LICENSES

RH-3301. General License for NRC-Approved Packages.

- a. A general license is hereby issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, e<u>C</u>ertificate of e<u>C</u>ompliance (CoC), or other approval has been issued by the U.S. Nuclear Regulatory Commission.
- b. This general license applies only to a licensee who has a quality assurance program approved by the Department U.S. Nuclear Regulatory Commission as satisfying the provisions of RH 3600, Part G, of this Section and the provisions of Subpart H of 10 CFR Part 71.
- c. <u>This general Each licensee applies only to a licensee who issued a general license under paragraph a. of this section shall:</u>
 - Has Maintain a copy of the certificate of compliance (CoC), or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to before shipment;
 - 2. Compliesy with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of this Parts A. F. and G of this Section;
 - 3. Submit in writing Bbefore the licensee's first use of the package, submits in writing to the U.S. Nuclear Regulatory Commission: ATTN: Document Control Desk, Director, <u>Division of Spent Fuel Project Office Storage and Transportation</u>, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.
- d. The <u>This</u> general license in <u>RH 3301.a.</u> applies only when the package approval authorizes use of the package under this general license.
- e. For a Type B or fissile material package, the design of which was approved by the U.S. Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19.

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RH-3304. General License for Use of Foreign Approved Package.

- A general license is hereby issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate, which that has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12 171.23.
- b. Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the Department U.S. Nuclear Regulatory Commission as satisfying the applicable provisions of RH 3600, Part G, of this Section and the provisions of Subpart H of 10 CFR Part 71.
- c. This general license applies only to shipments made to or from locations outside the United States.
- d. This general Each license applies only to a licensee who issued a general license under paragraph a. of this section shall:
 - Has Maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken prior to before shipment; and
 - Compliesy with the terms and conditions of the certificate and revalidation, and with <u>the</u> applicable requirements of this <u>Parts A</u>. <u>F</u>, and G of this Section. With respect to the quality assurance provisions of Part G of this Section, the licensee is exempt from design, construction, and fabrication considerations.

RH-3305. General License: Fissile Material.

a. A general license is issued to any licensee of the Department to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package which meets the standards of Part E of Section 4 entitled "Package Approval Standards" and 10 CFR Part 71, Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

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b. The general license applies only to a licensee who has a quality assurance program approved by the Department U.S. Nuclear Regulatory Commission as satisfying the provisions of RH-3600, Part G, of this Section and the provisions of Subpart H of 10 CFR Part 71. ...

RH-3306. General license: Plutonium-Beryllium Special Form Material.

- a. A general license is issued to any licensee of the Department to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package which meets the standards of Part E of Section 4 entitled "Package Approval Standards" and 10 CFR Part 71, Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).
- b. The general license applies only to a licensee who has a quality assurance program approved by the Department U.S. Nuclear Regulatory <u>Commission</u> as satisfying the provisions of RH-3600, Part G, of this Section and the provisions of Subpart H of 10 CFR Part 71, ...

PART F. OPERATING CONTROLS AND PROCEDURES

RH-3500. Applicability of Operating Controls and Procedures.

A licensee subject to this part <u>Section</u>, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with the requirements of this Part F, with the quality assurance requirements of Part G of this Section, and with the general provisions of Part A of these transportation regulations this Section.

RH-3502. Preliminary Determinations.

Before the first use of any packaging for the shipment of licensed material:, the licensee shall ascertain that the determinations in paragraphs (a) through (c) of 10 CFR 71.85 have been made.

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- a. The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;
- b: Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in²) gauge, the licensee shall test the containment system at an internal pressure at least fifty percent (50%) higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and
- c. The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U.S. Nuclear Regulatory Commission.

RH-3506. Records.

- a. Each licensee shall maintain, for a period of three (3) years after shipment, a record of each shipment of licensed material not exempt under 10 CFR 71.10 71.14, "Public Inspection of Application," showing where applicable:
 - 1. Identification of the packaging by model number and serial number:
 - 2. Verification that there were no significant defects in the packaging, as shipped; ...
- Each certificate holder shall maintain, for a period of three (3) years after the life of the packaging to which they apply, records identifying the packaging by model number, serial number, and date of manufacture.
- e. <u>b.</u> The licensee, certificate holder, and an applicant for a CoC, shall make available to the Department for inspection, upon reasonable notice, all records required by this Section. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.
- d. c. The licensee, certificate holder, and an applicant for a CoC shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained <u>shall</u> include, <u>but not be limited to</u>, results of the determinations required by RH-3502.; design, fabrication, and

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assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for three (3) years after the life of the packaging to which they <u>licensee</u> appl<u>yies</u>.

RH-3507. Inspection and Tests.

- a. The <u>Each</u> licensee, certificate holder, and applicant for a CoC shall permit afford to the U.S. Nuclear Regulatory Commission (NRC) Department, at all reasonable times, <u>opportunity</u> to inspect the licensed material, packaging, premises, and facilities in which the <u>wherein such</u> licensed material or packaging is used, provided, constructed, fabricated, tested, stored, or shipped.
- b. <u>Upon instruction from the Department, each The licensee, certificate</u> holder, and applicant for a CoC shall perform or cause to have performed, and <u>shall</u> permit the <u>NRC</u> <u>Department</u> to perform, any <u>such reasonable</u> tests <u>as the NRC Department</u> deems necessary or appropriate or necessary for the administration of these Regulations.
- c. The certificate-holder and applicant for a CoC shall notify the NRC, in accordance with 10 CFR 71.1 (RH 3003), forty-five (45) days in advance of starting fabrication of the first packaging under a CoC. This paragraph applies to any packaging used for the shipment of licensed-material which has either:

1. A decay heat load in excess of 5 kW; or

2:- A maximum normal operating pressure in excess of 103 kPa (15 lbf/in²) gauge.

RH-3508. Reports.

a. The <u>Each</u> licensee, after requesting the certificate holder's input, shall submit a written report to the Department and the U.S. Nuclear Regulatory Commission of:

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- 1. <u>Any finstances in which there is a significant reduction in the</u> effectiveness of any NRC approved Type B or Type AF packaging during use; or
- 2. Details of any defects with safety significance in any NRCapproved Type B or fissile material packaging, after first use-; or
- 3. <u>Any linstances in which the conditions of approval in the</u> Certificate of Compliance were not observed in making a shipment.
- b. The licensee shall submit a written report to the Department and the U.S. Nuclear Regulatory Commission of instances in which the conditions in the certificate of compliance were not followed during a shipment.
- e. b. Each licensee shall submit, in accordance with RH-3003, a <u>the</u> written report required by RH-3508.a. or RH-3508.b. paragraph a. of this section within sixty (60) days of the event or discovery of the event. The licensee shall also provide a copy of each report submitted to the Department and the NRC-to the applicable certificate holder. Written reports prepared under other regulations may be submitted to fulfill this requirement if the reports contain all the necessary information, and the appropriate distribution is made. Using an appropriate method listed in RH 3003.a., the licensee shall report to:

Arkansas Department of Health Radiation Control 4815 West Markham Street, Slot 30 Little Rock, Arkansas 72205-3867

and using an appropriate method listed in 10 CFR 71.1(a), the licensee shall also report to the U.S. Nuclear Regulatory Commission:

ATTN: Document Control-Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

These written reports must include the following:

- 1. A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.
- 2. A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of

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Section 4 and 10 CFR Part 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event.

- A. Status of components or systems that were inoperable at the start of the event and that contributed to the event;
- B. Dates and approximate times of occurrences;
- C. The cause of each component or system failure or personnel error, if known;
- D. The failure mode, mechanism, and effect of each failed component, if known;
- E. A list of systems or secondary functions that were also affected for failures of components with multiple functions;
- F. The method of discovery of each component or system failure or procedural error;
- G. For each human performance-related root cause, a discussion of the cause(s) and circumstances;
- H. The manufacturer and model number (or other identification) of each component that failed during the event; and
- I. For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.
- 3. An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.
- 4. A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.

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- 5. Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.
- 6. The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.
- 7. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

d. Report legibility.

The reports submitted by licensees and/or certificate holders under this section must be of sufficient quality to permit reproduction and micrographic processing.

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

As specified in RH-3509.b., c., and d. 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 RH 3509.b., c., and d. paragraphs b., c., and d. of <u>this section</u>, 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;

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- 2. The licensed material is being transported to or across a State boundary in <u>en</u> 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 A_1 value of the radionuclides as specified in Table A-1 of Appendix A to this Section <u>4</u> for special form radioactive material;
 - <u>B.</u> 3000 times the A₂ value of the radionuclides as specified in Table A-1 of Appendix A to this Section <u>4</u> for normal form radioactive material; or
 - C. 1000 TBq (27,000 Ci).

c. Procedures for submitting advance notification. ...

- 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).
 - B. The list of governor's designees and Tribal official's designees of participating Tribes will be published annually in the Federal Register on or about June 30 to reflect any changes in information. 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 Intergovernmental Liaison and Rulemaking Material

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Safety, State, Tribal, and Rulemaking Programs, Office of Federal and State Materials and Environmental Management Programs-Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

PART G. QUALITY ASSURANCE

RH-3600. Quality Assurance Requirements.

a. Purpose.

This Part describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this Part, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. The licensee, Each certificate holder, and applicant for a CoC package approval are is responsible for satisfying the quality assurance requirements as they that apply to design, fabrication, testing, and modification of packaging subject to this Part. Each licensee is responsible for satisfying the quality assurance provision requirements which that appliesy to its use of a packaging for the shipment of licensed material subject to this Part G or the Nuclear Regulatory Commissions' Subpart H to Part 71.

b. Establishment of program.

Each licensee, certificate holder, and applicant for a CoC Certificate of Compliance shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of Part G, "Quality Assurance," and U.S. Nuclear Regulatory Commission regulations 10 CFR Part 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee, certificate holder, and applicant for a CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.
c. Approval of program.

Before the use of any package for the shipment of licensed material subject to this Part G, each licensee shall obtain Department and/or U.S. Nuclear Regulatory Commission approval of its quality assurance program. Using an appropriate method listed in RH 3003.a. (10 CFR Part 71.1(a)), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this Part G (Subpart H of Part 71) are applicable and how they will be satisfied, by submitting the description to:

Arkansas Department of Health Radiation Control Section 4815 West Markham Street, Slot 30 Little Rock, Arkansas -72205-3867

and to the U.S. Nuclear Regulatory Commission:

ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

d. Previously approved programs.

A Department or U.S. Nuclear Regulatory Commission approved-quality assurance program that satisfies the applicable criteria of Part G of this Section, Subpart H of 10 CFR Part 71, Appendix B of 10 CFR Part 50, or Subpart G of 10 CFR Part 72, and that is established, maintained, and executed regarding transport packages, will be accepted as satisfying the requirements of RH-3600.b. Before first use, the licensee, certificate holder, and applicant for a CoC shall notify the U.S. Nuclear Regulatory Commission in accordance with 10 CFR Part 71.1 of its intent to apply its previously approved Part G of this Section, Appendix B of Part 50, or Subpart G of Part 72 quality assurance program to transportation activities. The licensee, certificate holder, and applicant for a CoC shall identify the program by date of submittal to the U.S. Nuclear Regulatory Commission, Docket Number, and date of U.S. Nuclear Regulatory Commission approval.

e. d. Radiography containers.

A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of RH-1801.i.2. or equivalent

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<u>U.S.</u> Nuclear Regulatory Commission or Agreement State requirement, is deemed to satisfy the requirements of RH-3301.b. and RH-3600.b.

RH-3601. Quality Assurance Organization.

- a. The licensee¹⁴, certificate holder, and applicant for a CoC Certificate of Compliance shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.
- b. The quality assurance functions are:
 - 1. Assuring that an appropriate quality assurance program is established and effectively executed; and
 - 2. Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed. ...

RH-3602. Quality Assurance Program.

- a. The licensee, certificate holder, and applicant for a CoC Certificate of Compliance shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the Department requirements found in Part G, "Quality Assurance," and U.S. Nuclear Regulatory Commission regulations 10 CFR Part 71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, certificate holder, and applicant for a CoC shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.
- b. The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent

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consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee, certificate holder, and applicant for a CoC shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

- c. The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:
 - 1. The impact of malfunction or failure of the item to safety;
 - 2. The design and fabrication complexity or uniqueness of the item;
 - 3. The need for special controls and surveillance over processes and equipment;
 - 4. The degree to which functional compliance can be demonstrated by inspection or test; and
 - 5. The quality history and degree of standardization of the item.
- d. The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of the quality assurance program they are executing.
- e. Changes to quality assurance program.
 - 1. Each quality assurance program approval holder shall submit to the U.S. Nuclear Regulatory Commission, in accordance with 10 CFR 71.1(a), a description of a proposed change to its NRC-approved quality assurance program that will reduce commitments in the

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program description as approved by the NRC. The quality assurance program approval holder shall not implement the change before receiving NRC approval.

A. The description of a proposed change to the NRC-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of Subpart H of 10 CFR Part 71.

B. Reserved.

- 2. Each quality assurance program approval holder may change a previously approved quality assurance program without prior NRC approval, if the change does not reduce the commitments in the quality assurance program previously approved by the NRC. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the NRC every 24 months, in accordance with 10 CFR 71.1(a). In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:
 - A. The use of a quality assurance standard approved by the NRC that is more recent than the quality assurance standard in the certificate holder's or applicant's current quality assurance program at the time of the change:
 - B. The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities:
 - C. The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities:
 - D. The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality

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assurance program approval holder has committed to on record; and

- E. Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.
- 3. Each quality assurance program approval holder shall maintain records of quality assurance program changes.

RH-3603. Handling, Storage, and Shipping Control.

The licensee, certificate holder, and applicant for a CoC Certificate of Compliance shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

RH-3604. Inspection, Test, and Operating Status.

- a. The licensee, certificate holder, and applicant for a CoC Certificate of Compliance shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.
- b. The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

RH-3605. Nonconforming Materials, Parts, or Components.

The licensee, certificate holder, and applicant for a CoC Certificate of Compliance shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for

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identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

RH-3606. Corrective Action.

The licensee, certificate holder, and applicant for a CoC Certificate of Compliance shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

RH-3607. Quality Assurance Records.

The licensee, certificate holder, and applicant for a CoC Certificate of Compliance shall maintain sufficient written records to describe the activities affecting quality. The These records must include changes to the quality assurance program as required by RH-3602.e.: the instructions, procedures, and drawings required by U.S. Nuclear Regulatory Commission regulation 10 CFR 71.111 to prescribe quality assurance activities: and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures which that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder. and applicant for a CoC shall retain these records for three (3) years beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures, or instructions is superseded, the licensee, certificate holder, and applicant for a CoC shall retain the superseded material for three (3) years after it is superseded.

RH-3608. Audits.

The licensee, certificate holder, and applicant for a CoC Certificate of Compliance shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained

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personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, must be taken where indicated.

APPENDIX A TO SECTION 4

DETERMINATION OF A₁ AND A₂...

- IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:
 - a. For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_{i} \frac{B(i)}{A_{1}(i)} \le 1$$

where B(i) is the activity of radionuclide i in special form, and $A_1(i)$ is the A_1 value for radionuclide $\frac{1}{2}$.

b. For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_{i} \frac{B(i)}{A_2(i)} \le 1$$

where B(i) is the activity of radionuclide i in normal form, and $A_2(i)$ is the A_2 value for radionuclide i.

c. If the package contains both special and normal form radioactive material, the activity that may be transported in a Type A package is as follows:

$$\sum_{i} \frac{B(i)}{A_{1}(i)} + \sum_{j} \frac{C(j)}{A_{2}(j)} \le 1$$

where B(i) is the activity of radionuclide i as special form radioactive material $A_1(i)$ is the A_1 value for radionuclide i. C(j) is the activity of radionuclide j as normal form radioactive material, and $A_2(j)$ is the A_2 value for radionuclide j.

e.d. Alternatively, the A₁ value for mixtures of special form material may be determined as follows:

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A₁ for mixture =
$$\frac{1}{\sum_{i} \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity for radionuclide \underline{Ii} in the mixture, and $A_1(i)$ is the appropriate A_1 value for radionuclide \underline{Ii} .

d.e. Alternatively, the A₂ value for mixtures of normal form material may be determined as follows:

A₂ for mixture =
$$\frac{1}{\sum_{i} \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity for radionuclide $\underline{I}_{\underline{i}}$ in the mixture, and $A_2(i)$ is the appropriate A_2 value for radionuclide $\underline{I}_{\underline{i}}$.

e.<u>f.</u> The exempt activity concentration for mixtures of nuclides may be determined as follows:

Exempt activity concentration for mixture = $\frac{1}{\sum_{i=1}^{n} \frac{f(i)}{[A](i)}}$

where f(i) is the fraction of activity concentration of radionuclide \underline{Ii} in the mixture, and $[A](\underline{i})$ is the activity concentration for exempt material containing radionuclide \underline{Ii} .

f.g. The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

Exempt consignment activity limit for mixture = $\frac{1}{\sum \frac{f(i)}{A(i)}}$

where f(i) is the fraction of activity of radionuclide $I_{\underline{i}}$ in the mixture, and $A(\underline{i})$ is the activity limit for exempt consignments for radionuclide $I_{\underline{i}}$.

V. <u>a.</u> When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped, and the lowest A₁ or A₂ value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. of this Appendix. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using

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the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters, respectively.

b. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest [A] (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. of this Appendix. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest [A] or A values for the alpha emitters and beta/gamma emitters. respectively.

Symbol of	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	(TD -)	$A_2(Ci)^b$	Specific activity	
radionuclide				A2(1Dq)	A ₂ (CI)	(TBq/g)	(Ci/g)
• • • •			1 Maria		Of the Constant of		ł
Cf-252 (h)		5.0X10 ⁻² 1.0X10 ⁻¹	1.4 <u>2.7</u>	3.0X10 ⁻³	8.1X10 ⁻²	2.0X10 ¹	5.4X10 ²
•••				1.465			
Ir-192 (c)		<u>°</u> 1.0	^c 2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.4X10 ²	9.2X10 ³
<u>Kr-79</u>	Krypton (36)	<u>4.0</u>	1.1×10^{2}	2.0	5.4×10^{1}	4.2×10^4	1.1×10^{6}
Kr-81	Krypton (36)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	7.8X10 ⁻⁴	2.1X10 ⁻²
	AV AV						
Mo-99 (a) (<u>ih</u>)		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.8X10 ⁴	4.8X10 ⁵
					The State of the S		

TABLE A-1—A1 AND A2 VALUES FOR RADIONUCLIDES

A₁ and/or A₂ values include contributions from daughter nuclides with half-lives less than 10 days, as listed in the following:-

Mg-28	A1-28
Ca-47	Sc-47
Ti-44	Sc-44
Fe-52	Mn-52m

Fe-60	Co-60m
Zn-69m	Zn-69
Ge-68	Ga-68
Rb-83	Kr-83m
Sr-82	Rb-82
Sr-90	Y-90
Sr-91	Y-91m
Sr-92	Y-92
Y-87	Sr-87m
Zr-95	Nb-95m
Zr-97	Nb-97m, Nb-97
Mo-99	Tc-99m
Tc-95m	Tc-95
Tc-96m	Tc-96
Ru-103	Rh-103m
Ru-106	Rh-106
Pd-103	Rh-103m
Ag-108m	Ag-108
Ag-110m	Ag-110
Cd-115	In-115m
In-114m	In-114
Sn-113	In-113m
Sn-121m	Sn-121
Sn-126	Sb-126m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
I-135	Xe-135m
Xe-122	I-122
Cs-137	Ba-137m
Ba-131	Cs-131
Ba-140	La-140
Ce-144	Pr-144m, Pr-144
Pm-148m	Pm-148

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Gd-146	Eu-146				
Dy-166	Но-166				
Hf-172	Lu-172				
W-178	Ta-178				
W-188	Re-188				
Re-189	Os-189m				
Os-194	Ir-194				
Ir-189	Os-189m				
Pt-188	Ir-188				
Hg-194	Au-194				
Hg-195m	Hg-195				
Pb-210	Bi-210				
Pb-212	Bi-212, TI-208, Po-212				
Bi-210m	T1-206				
Bi-212	TI-208, Po-212				
At-211	Po-211				
Rn-222	Po-218, Pb-214, At-218, Bi-214, Po-214				
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Po-211, Tl-207				
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212				
Ra-225	Ac-225, Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209				
Ra-226	Rn-222, Po-218, Pb-214, At-218, Bi-214, Po-214				
Ra-228	Ac-228				
Ac-225	Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209				
Ac-227	Fr-223				
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212				
Th-234	Pa-234m, Pa-234				
Pa-230	Ac-226, Th-226, Fr-222, Ra-222, Rn-218, Po-214				
U-230	Th-226, Ra-222, Rn-218, Po-214				
U-235	Th-231				
Pu-241	U-237				
Pu-244	U-240, Np-240m				
Am-242m	Am-242, Np-238				
Am-243	Np-239				
Cm-247	Pu-243				
Bk-249	Am-245				

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-				
CF 252	Cm-249			
CI-200	CIII-249			

- ^b The values of A₁ and A₂ in Curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq). See Appendix A to Section 4 Determination of A₁ and A₂, Section I.
- ^e The quantity activity of Ir-192 in special form may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.
- ^d These values apply only to compounds of uranium that take the chemical form of UF_6 , UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.
- [°] These values apply only to compounds of uranium that take the chemical form of UO₃, UF₄, UCl₄ and hexavalent compounds in both normal and accident conditions of transport.
- ^f These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.
- ^g These values apply to unirradiated uranium only.

^h $A_1 = 0.1$ TBq (2.7 Ci) and $A_2 = 0.001$ TBq (0.027 Ci) for Cf 252 for domestic use.

^{ih} A₂ = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

TABLE A-2—EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)	
	No.					
<u>Kr-79</u>	Krypton (36)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁵	2.7X10 ⁻⁶	
Kr-81	Krypton (36)	1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴	
Te-121m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ^{5<u>6</u>}	2.7X10 ⁻⁶⁵	

^b Parent nuclides and their progeny included in secular equilibrium are listed in the following as follows:

Sr-90	Y-90	
Zr-93	Nb-93m	
Zr-97	Nb-97	
Ru-106	Rh-106	

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Ag-108m	<u>Ag-108</u>
Cs-137	Ba-137m
Ce-13 4	La 134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	TI-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po 216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, TI-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th 226	Ra 222, Rn 218, Po 214
Th-228	Ra-224, Rn-220, Po-216. Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214 Pb-210, Bi-210, Po-210
U 240	Np 240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

	A ₁		A ₂		Activity	Activity	Activity	Activity	
Contents	(TBq)	(Ci)	(TBq)	(Ci)	concentra tion for exempt material (Bq/g)	concentra tion for exempt material (Ci/g)	limits for exempt consignments (Bq)	limits for exempt consignments (Ci)	
Only beta or gamma emitting radionuclides are known to be present	1 x 10 ⁻¹	2.7 x 10 ⁰	2 x 10 ⁻²	5.4 x 10 ⁻¹	1 x 10 ¹	2.7 x 10 ⁻¹⁰	1 x 10 ⁴	2.7 x10 ⁻⁷	
Only a <u>A</u> lpha emitting radionuclides, <u>but no</u> <u>neutron</u> <u>emitters</u> are known to be present ^a	2 x 10 ⁻¹	5.4 x 10 ⁰	9 x 10 ⁻⁵	2.4 x 10 ⁻³	1 x 10'	2.7 x 10 ⁻¹²	1×10^3	2.7 x10 ⁻⁸	
Neutron emitting nuclides are known to be present or N <u>n</u> o relevant data are available	1 x 10 ⁻³	2.7 x 10 ⁻²	9 x 10 ⁻⁵	2.4 x 10 ⁻³	1 x 10 ⁻¹	2.7 x 10 ⁻¹²	1 x 10 ³	2.7 x 10 ⁻⁸	

TABLE A-3—GENERAL VALUES FOR A1 AND A2

^a If beta or gamma emitting nuclides are known to be present, the A₁ value of 0.1 TBq (2.7 Ci) should be used.

FOOTNOTES TO SECTION 4

 $[\]frac{1}{2}$ While the term "licensee" is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued.

SECTION 6. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

PART B. DEFINITIONS

RH-5100. **Definitions.**

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

PART C. LICENSES

RH-5204. Issuance of Particle Accelerator Licenses.

- a. Upon a determination that an application meets the requirements of the Act and these Regulations of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary to effectuate the purposes of the Act.
 - The Department may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's use of a particle accelerator as it deems appropriate or necessary in order to:
 - 1. Protect health or to minimize danger to life or property; and
 - Require such reports and the keeping of such records, and to provide for such inspection of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and these Regulations thereunder.
- RH-5205. Specific Terms and Conditions of Licenses....
 - d. The Department may incorporate in any license at the time of issuance. or thereafter by appropriate rule, regulation, or order, such additional

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requirements and conditions with respect to the licensee's use of a particle accelerator as it deems appropriate or necessary in order to:

- 1. Protect health or to minimize danger to life or property; and
- 2. Require such reports and the keeping of such records, and to provide for such inspection of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and these Regulations thereunder.
- d. e. Bankruptcy Notification. ...

PART G. EXEMPTIONS, ADDITIONAL REQUIREMENTS, INSPECTIONS, AND TESTS

RH-5603. Tests.

<u>Upon instruction from the Department</u>, <u>Eeach licensee shall perform or cause to</u> <u>have performed upon instructions from the Department</u>, or <u>and</u> shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary, including, but not limited to, tests of:

- a. Sources of radiation;
- b. Facilities wherein sources of radiation are used or stored;
- c. Radiation detection and monitoring instruments; and
- d. Other equipment and devices used in connection with utilization or storage of licensed sources of radiation.

PART I. RECORDS

RH-5802. Record Maintenance.

Records which must be maintained pursuant to Each record required by this Section must be legible throughout the specified retention period. The record may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is

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capable of producing a clear and legible copy after storage for the period specified by Department regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

SECTION 8. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

PART A. GENERAL

RH-7002. **Definitions**.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

PART B. LICENSES

RH-7015. Commencement of Construction.

The applicant may not begin construction of a new irradiator prior to the submission to the Department of both an application for a license for the irradiator and the fee required. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparations, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and having no bearing on the issuance of a license with respect to the requirements of the Atomic Energy Act of 1954, as amended, and rules, regulations, and orders issued under the Act.

PART C. DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS

RH-7021. Performance Criteria for Sealed Sources.

- a. **Requirements**. Sealed sources installed after July 1, 1993 January 1, 1997:
 - Must have a certificate of registration issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 of 10 CFR Part 32 or by an Agreement State pursuant to provisions comparable to 10 CFR 32.210;
 - 2. Must be doubly encapsulated:
 - 3. Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wetsource-storage or wet-source-change irradiator;
 - 4. Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and
 - 5. In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in RH 7021.b. through RH-7021.g paragraphs b. through g. of this section. ...

RH-7033. Irradiator Pools.

- a. For licenses initially issued after July 1, 1993 January 1, 1997, irradiator pools must either:
 - 1. Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or
 - 2. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.
- b. For licenses initially issued after July 1, 1993 January 1, 1997, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that

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could act as siphons must have siphons breakers to prevent the siphoning of pool water. ...

RH-7039. Design Requirements.

Irradiators whose construction begins after July 1, 1993 January 1, 1997, must meet the design requirements of this section. ...

RH-7041. Construction Monitoring and Acceptance Testing.

These requirements must be met for irradiators whose construction begins after July 1, 1993 January 1, 1997. The requirements must be met prior to loading sources. ...

PART D. RADIATION SAFETY REQUIREMENTS FOR THE OPERATION OF IRRADIATORS

RH-7059. Detection of Leaking Sources. ...

If a leaking source is detected, the licensee shall arrange to remove the c. leaking source from service and have it decontaminated, repaired, or disposed of by a Department, U.S. Nuclear Regulatory Commission, or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by a Department, U.S. Nuclear Regulatory Commission, or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table II-Column 2 of Appendix G to Section 3. (See RH-1502.e. through RH-1502.g. 601. for reporting requirements.)

PART E. RECORDS AND REPORTS

RH-7083. Reports. ...

b. The report must include a telephone report within 24 (twenty-four) (24) 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.2. 601.c.2.

SECTION 9. USE OF RADIONUCLIDES IN THE HEALING ARTS

PART B. DEFINITIONS

RH- 8100. **Definitions**.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

SECTION 11. THERAPEUTIC RADIATION MACHINES

PART B. DEFINITIONS

RH-10100. Definitions.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

PART C. ADMINISTRATIVE REQUIREMENTS

- RH-10200. General Administrative Requirements for Facilities Using Therapeutic Radiation Machines. ...
 - m. Records retention.

All records required by Section 11 shall be retained until disposal is authorized by the Department unless another retention period is specifically authorized in Section 6 or Section 11. All required records shall be retained in an active file from at least the time of generation until the next Department inspection. Any required record generated prior to the last Department inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Department authorizes final disposal.

m. Record retention periods.

- 1. Each licensee or registrant shall retain each record that is required by this Section or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Department terminates each license or registration that authorizes the activity that is subject to the recordkeeping requirement.
- 2. If there is a conflict between the Department's regulations in this Section, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this Section for such records shall apply unless the Department, pursuant to RH-10005, has granted a specific exemption from the record retention requirements specified in the regulations in this Section.

n. Record maintenance.

Each record required by this Section must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The

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licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

RH-10308. Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage.

A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

- a. The applicant or licensee/registrant has, at a minimum, provided the Department with:
 - 1. A completed Department form "Application for Registration of Radiation Machine(s)" RC FORM 200. "Radiation Machine Facility Registration": ...

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

PART A. GENERAL

RH-11005. Definitions.

Security zone - Any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material <u>during use or storage</u>.

PART B.

BACKGROUND INVESTIGATIONS AND ACCESS AUTHORIZATION PROGRAM

- RH-11023. Access Authorization Program Requirements.
 - b. Reviewing officials.

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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. 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, 11545 Rockville Pike, Rockville, Maryland 20852-2738, ATTN: Criminal History Program, Mail Stop T-03B46M, 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 Information Services the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-301-415-7513, or by email to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at http://www.nrc.gov/site-help/esubmittals.html.

PART C. PHYSICAL PROTECTION REQUIREMENTS DURING USE

RH-11041. Security Program.

- a. Applicability.
 - 1. Each licensee that possesses an aggregated category 1 or category

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2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this Part.

- 2. An applicant for a new license and each licensee that would become newly subject to the requirements of this Part upon application for modification of its license shall implement the requirements of this Part, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.
- 3. Any licensee that has not previously implemented the Security Orders security requirements or been subject to the provisions of Part C shall provide written notification to the Department as specified in RH-11007. at least ninety (90) days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

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. ...
- 7. When not in use, the licensee shall store its security plan, and 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.

PART D. PHYSICAL PROTECTION IN TRANSIT

RH-11075. Preplanning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material.

a. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or

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storage shall:

а.

- 1. Preplan and coordinate shipment arrival and departure times with the receiving licensee;
- 2. Preplan and coordinate shipment information with the <u>Department</u> and with the povernor or the governor's designee of any State through which the shipment will pass to:
 - A. Discuss the State's intention to provide law enforcement escorts; and
 - B. Identify safe havens; and
- 3. Document the preplanning and coordination activities. ...

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.

Procedures for submitting advance notification.

 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 governors and governors' designees, is available on the U.S. Nuclear Regulatory Commission website at-http://nrestp.ornl.gov/special/designee.pdf
<u>https://scp.nrc.gov/special/designee.pdf</u>
<u>h</u>

Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The notification to the Department may be made by fax to 1-501-280-4407.

Υ.