

Ms. Vicki Thomas
Executive Director
Joint Committee on Administrative Rules
700 Stratton Office Building
Springfield, Illinois 62706

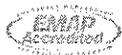
Re: 32 Ill. Adm. Code 331

Dear Ms. Thomas:

This SECOND NOTICE is for the Illinois Emergency Management Agency's Proposed Amendments pertaining to Fees for Radioactive Material Licensees.

In accordance with Sections 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Illinois Emergency Management Agency states as follows:

- 1) The name of the agency is the Illinois Emergency Management Agency.
- 2) The title and citation of the proposed amendments are Fees for Radioactive Material Licensees, 32 Ill. Adm. Code 331.
- 3) The First Notice was published on May 15, 2015, in Vol. 39, Issue 20 of the Illinois Register, beginning at p. 6824.
- 4) The Agency has accepted all changes made by JCAR and they are included in the text.
- 5) The Agency received notification from the Office of the Secretary of State, Administrative Code Division that the Division had reviewed the Proposed Rules and found that the rules comply with codification requirements. (See Attachment A: Memorandum dated May 8, 2015)





Illinois Emergency Management Agency

James K. Joseph, Director

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- 6) The Proposed Amendment does not contain incorporations by reference pursuant to Section 100/5-75 of the Illinois Administrative Procedure Act.
- 7) The Agency received no comments regarding this rulemaking from businesses identifying themselves as small businesses pursuant to Section 100/5-40(c) of the IAPA. Therefore, a Final Regulatory Flexibility Analysis was not prepared.
- 8) In order to comply with the requirements of Section 100/5-30 of the Administrative Procedure Act and 1 Ill. Adm. Code 220.285, the Agency emailed a copy of the proposed Amendments to the members of the affected community.
- 9) The Agency did not receive any comments regarding this rulemaking during the First Notice Period.
- 10) This Amendment will: update references in correlation to an amendment to 32 Illinois Administrative Code 330.
- 11) Joint Committee questions may be directed to Louise Conway, Staff Attorney at 785-9876 or Traci Burton, Paralegal Assistant at 785-9860, telefax number 524-3698.
- 13) The Joint Committee on Administrative Rules did not request the Agency to complete a State Mandates Act Questionnaire.

Sincerely,

Traci Burton
Rules Coordinator



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TITLE 32: ENERGY
CHAPTER II: ILLINOIS EMERGENCY MANAGEMENT AGENCY
SUBCHAPTER b: RADIATION PROTECTION

PART 331
FEES FOR RADIOACTIVE MATERIAL LICENSEES

Section	
331.10	Purpose
331.20	Scope
331.30	Definitions
331.110	Exemptions
331.115	Radioactive Material Recovery and Remediation Fee
331.120	Payment of Fees
331.125	Implementation (Repealed)
331.130	Refunds of Full Cost Recovery Deposits
331.200	Full Cost Recovery
331.210	Schedule of Fees For Radioactive Material Licenses (Repealed)
331.310	Failure by Applicant or Licensee to Pay Prescribed Fee
331.APPENDIX A	Schedule of License Fees (Repealed)
331.APPENDIX B	Fee Schedule For Radioactive Material Licenses (Repealed)
331.APPENDIX C	Fee Schedule For Sealed Source And Device Evaluations (Repealed)
331.APPENDIX D	Fee Schedule For Radioactive Material Licenses (Repealed)
331.APPENDIX E	Primary Material Use Categories for Radioactive Material Licensees
331.APPENDIX F	Fee Schedule for Radioactive Material Licensees

AUTHORITY: Implementing and authorized by Section 11 of the Radiation Protection Act of 1990 [420 ILCS 40/11].

SOURCE: Adopted at 10 Ill. Reg. 17239, effective September 25, 1986; amended at 11 Ill. Reg. 20570, effective January 1, 1988; amended at 15 Ill. Reg. 90, effective January 1, 1991; amended at 16 Ill. Reg. 11479, effective July 7, 1992; amended at 18 Ill. Reg. 12131, effective August 1, 1994; emergency amendment at 21 Ill. Reg. 4309, effective March 19, 1997, for a maximum of 150 days; amended at 21 Ill. Reg. 10968, effective July 28, 1997; amended at 22 Ill. Reg. 6951, effective April 1, 1998; amended at 23 Ill. Reg. 5585, effective April 23, 1999; amended at 25 Ill. Reg. 8266, effective July 1, 2001; amended at 26 Ill. Reg. 14274, effective September 16, 2002; recodified from the Department of Nuclear Safety to the Illinois Emergency Management Agency at 27 Ill. Reg. 13641; amended at 33 Ill. Reg. 4298, effective March 9, 2009; amended at 36 Ill. Reg. 17387, effective November 30, 2012; amended at 37 Ill. Reg. 20225, effective December 9, 2013; amended at 39 Ill. Reg. _____, effective _____.

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Section 331.120 Payment of Fees

Fees shall be assessed and paid as follows:

- a) For categories of specific licenses that are shown to have an annual fee in Appendix F, applicants and licensees shall be billed as described in this subsection (a). Payment is due within 60 days after the date of billing. Fees shall be assessed as follows:
 - 1) Annual fees: Unless a license or amendment application is exempt under Section 331.110, or the license fee is to be based on full cost recovery (see Appendix F), each licensee shall be assessed the fees specified in Appendix F for the primary material use category authorized by the license annually.
 - 2) Annual remote site fee: For each remote site listed on a specific radioactive material license, where radioactive material is stored or used under the same license, the applicant shall annually be assessed the amount specified in Appendix F for each remote site that corresponds to the highest material use category authorized by the license for each site.
 - 3) Changing the primary material use category or a remote site category. An application for amendment to a materials license that would change the primary material use category or a remote site category to a new category with a higher fee shall be assessed fees for the incremental difference between the applicable annual fees and the portion of the billing year remaining from the time the amendment is approved by the Agency.
 - 4) The annual and remote site fees listed in Appendix F are nonrefundable, and are assessed based on a 12 month period.
 - 5) Applicants requesting new licenses shall be assessed fees for the applicable Primary category as specified in Appendix F. Applicants shall be assessed fees for the portion of the billing year remaining from the time the application is received in the Agency to the end of the billing year.
 - 6) An educational institution (as defined in Section 331.30) that seeks or has a license authorizing possession and use of radioactive material for human use or veterinary use, or remunerated leak testing or instrument calibration services to others shall pay 100% of the highest primary material use category for which a fee is due.

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- b) Recovery and remediation fees listed in Appendix F are nonrefundable and shall be billed along with the new license application fee described in subsection (a)(5) of this Section. The second installment, if required by Section 331.115, shall be assessed at the next billing date.
- c) For categories of licenses that have fees based on full cost recovery, as listed in Appendix F, fees shall be assessed for all new applications, evaluations, inspections, amendments (including amendments to terminate or renew a license) and for monitoring of unlicensed properties contaminated with byproduct material (as defined in 32 Ill. Adm. Code 332.20) and assessing the decommissioning and decontamination activities at those properties. Fees based on full cost recovery shall be assessed as follows:
 - 1) A licensee or applicant shall be assessed the deposit prescribed in Appendix F when the first application is received by the Agency after July 1, 2001. Licensees that already have adequate deposits on file with the Agency shall not be required to resubmit a deposit except for sealed source or device evaluations as indicated in subsection (d) ~~of this Section~~. This deposit shall be held by the Agency until a new license request has been denied by the Agency or withdrawn by the applicant, or an existing license is terminated. The deposit shall be refunded in accordance with Section 331.130.
 - 2) The licensee may be billed quarterly, or when the Agency has incurred unpaid full cost expenses (as defined in Section 331.200(c)) in excess of the amount of the deposit, or upon completion of a license action (such as an amendment or renewal). Each bill shall identify the actions and the costs related to each. Payment is due within 60 days after the date of billing.
- d) For evaluations of new sealed sources and devices, and amendments to existing sealed sources and device evaluations, fees shall be assessed based on the full cost of review. Each application for an evaluation of a new sealed source or device, or for an amendment to an existing sealed source or device evaluation, shall be accompanied by a deposit in the amount of \$500. The applicant shall be billed or issued a refund upon the completion of the review. Each bill shall identify the actions and the costs related to each. Payment is due within 60 days after the date of billing.
- e) For evaluations of financial assurance reclamation plans and cost estimates submitted to the Agency, fees for Agency review shall be assessed based on the

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full cost of review time in excess of two hours. Payment is due within 60 days after the date of billing.

- f) For categories of licenses not exempted in Section 331.110, and licenses not subject to full cost recovery as described in Appendix F, full cost recovery fees shall be assessed for Agency confirmatory measurements and Agency assessment of decommissioning and decontamination activities associated with the termination of a license or use of a site. The licensee shall be billed upon the completion of the assessment and prior to removal of a site from the license or termination of the license. Each bill shall identify the actions and the costs related to each. Payment is due within 60 days after the date of the billing.
- g) General license fees. Fees are nonrefundable and payment is due within 60 days after the date of the billing. The Agency shall assess fees:
 - 1) Annually to each person who receives, acquires, possesses or uses a prepackaged unit for in vitro clinical or laboratory testing pursuant to the general license provided by 32 Ill. Adm. Code 330.220(e)(1); and
 - 2) Annually to each person who receives, acquires, possesses or uses a generally licensed device and is required to register pursuant to 32 Ill. Adm. Code 330.220(a)(4).
- h) Sealed source and device evaluation maintenance fee. Each person having an active sealed source or device evaluation on file with the Agency, except for custom sealed source and device evaluations, shall be billed the amount specified in Appendix F annually for each active evaluation sheet on file with the Agency. Fees are nonrefundable and payment is due within 60 days after the date of the billing.
- i) Reciprocity fees. Each person generally licensed under 32 Ill. Adm. Code 330.900 for reciprocal recognition of an out-of-state specific license shall be assessed fees for the applicable annual license fee for the primary material use category indicated in Appendix F. Fees are nonrefundable and payment is due within 60 days after the date of the billing. The assessed billing period shall be for the 12 consecutive months following the licensee's first use under the general license. If, at the end of the 12 month period, the licensee is not using the general license, no additional fees are due until licensed activities commence again.

AGENCY NOTE: Reciprocity licensees are also subject to recovery and remediation fees specified in Section 331.115.

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- j) Fee payments. Payments shall be by check or money order made payable to the Illinois Emergency Management Agency.

(Source: Amended at 39 Ill. Reg. _____, effective _____)

Section 331.APPENDIX E Primary Material Use Categories for Radioactive Material Licensees

<u>Fee Category</u>	<u>Primary Material Use Category Description</u>
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MANUFACTURING/DISTRIBUTION

- | | |
|-------|--|
| 201A. | Broad Scope Manufacturing and/or Distributions – licenses (as specified in 32 Ill. Adm. Code 330.270) for possession and use of radioactive material for research and development, and processing or manufacturing radioactive material or items containing radioactive material for commercial distribution, including, but not limited to, nuclear pharmacy operations, or manufacturing of a chemical mixture, compound, solution or alloy which is listed in 32 Ill. Adm. Code 330.30. |
| 201B. | Specific Manufacturing and /or Distribution – licenses for possession and use of greater than 37 GBq (1 Ci) of radioactive material for research and development, and processing or manufacturing radioactive material or items containing radioactive material for commercial distribution, including, but not limited to, manufacturing of a chemical mixture, compound, solution or alloy which is listed in 32 Ill. Adm. Code 330.30. |
| 201C. | Nuclear Pharmacy and Limited Manufacturing and/or Distribution – this category of radioactive material licenses addresses two similar types of licenses, either: <ul style="list-style-type: none">i) nuclear pharmacy licenses for possession, use and distribution of radiopharmaceuticals and sealed sources to persons authorized pursuant to 32 Ill. Adm. Code 335; orii) Licenses for possession and use of not more than 37 GBq (1 Ci) of radioactive material for research and development, and processing or manufacturing of radioactive material for limited commercial distribution, including, but not limited to, manufacturing of a chemical mixture, radiolabeled compound, solution or alloy that is listed in 32 Ill. Adm. Code 330.30. |
| 201D. | Distribution – licenses authorizing receipt, storage and distribution of radioactive material or items containing radioactive material, not |

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involving processing or manufacturing of radioactive material.

IRRADIATORS

- 202A. Category I Irradiator – licenses for possession and use of radioactive material as sealed sources in a gamma irradiator in which the sealed source is completely contained in a dry container constructed of solid material, the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is not physically possible because of the design of the irradiator.
- 202B. Category II, III or IV Irradiator – licenses for possession and use of less than 370 TBq (10,000 Ci) of radioactive material as sealed sources in a controlled human access gamma irradiator in which the sealed source is either:
- i) contained in a dry container constructed of solid materials, is fully shielded when not in use and is exposed within a radiation volume that is maintained inaccessible during use by an entry control system;
 - ii) Contained in a storage pool, the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is physically restricted in its design configuration and proper mode of use; or
 - iii) Contained in a storage pool, is fully shielded when not in use and is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.
- 202C. Category II, III or IV Irradiator – licenses for possession and use of 370 TBq (10,000 Ci) or more of radioactive material as sealed sources in a controlled human access gamma irradiator in which the sealed source is either:
- i) Contained in a dry container constructed of solid materials, is fully shielded when not in use and is exposed within a radiation volume that is maintained inaccessible during use by an entry control system;
 - ii) Contained in a storage pool, the sealed source is shielded at all times, and human access to the sealed source and the volume

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undergoing irradiation is physically restricted in its design configuration and proper mode of use; or

- iii) Contained in a storage pool, is fully shielded when not in use and is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

RESEARCH AND DEVELOPMENT

- 203A. Broad Scope Research and Development – licenses (as specified in 32 Ill. Adm. Code 330.270) for possession and use of radioactive material for research and development that do not authorize commercial distribution.
- 203B. Other Research and Development – licenses for possession and use of radioactive material for research and development that do not authorize commercial distribution.

AGENCY NOTE: The Agency will allow the non-commercial distribution of material to other licensees for the purpose of collaborative research and development.

PORTABLE AND FIXED GAUGES

- 204A. Gas Chromatographs and Fixed X-Ray Fluorescence Analyzers – specific licenses for possession and use of radioactive material in sealed sources for use in gas chromatographs or fixed x-ray fluorescence analyzers.
- 204B. Portable Gauges and Portable X-Ray Fluorescence Analyzers – specific licenses for possession and use of radioactive material as sealed sources for use in portable gauges or x-ray fluorescence analyzers.
- 204C. Fixed Gauges – specific licenses for possession and use of radioactive material as sealed sources for use in fixed gauges.

SERVICE

- 205A. Service – licenses that authorize services for other persons, including, but not limited to, testing of sealed sources for leakage or contamination, instrument calibration and sample analysis, but not including waste disposal transportation or radioactive waste broker services. Medical service licensees include licensees that only transport sources and equipment to a client's facility, but do not authorize the medical use or administration of that material. The medical use or administration of

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radioactive material to humans or animals shall be performed under a specific medical use license.

- 205B. Nuclear Laundries – licenses for commercial collection and laundering of items contaminated with radioactive material.
- 205C. Decontamination Facilities – licenses that authorize receipt of items contaminated with radioactive material for the purpose of decontaminating such items.

WIRELINE (Well-Logging)

206. Wireline Service Operations (as defined in 32 Ill. Ad. Code 351) – licenses specifically authorizing use of radioactive material for wireline services, well surveys and tracer studies.

INDUSTRIAL RADIOGRAPHY

207. Industrial Radiography (as defined in 32 Ill. Adm. Code 350) – licenses specifically authorizing use of radioactive material for industrial radiography at permanent or temporary jobsites.

MEDICAL/VETERINARY

- 208A. Broad Scope Medical/Veterinary Use – ~~broad~~Broad scope licenses (as specified in 32 Ill. Adm. Code 330.270) authorizing diagnostic and/or therapeutic veterinary or human use of radioactive material. These licenses may include research and development, or use of radioactive material in sealed sources contained in teletherapy or high dose rate remote afterloader devices.
- 208B. Medical/Veterinary Use Including Teletherapy and/or High Dose Rate Remote Afterloader – licenses for diagnostic and/or therapeutic human or veterinary use of radioactive material that include authorization for possession and use of radioactive material as sealed sources contained in teletherapy or high dose rate remote afterloader devices for medical or veterinary use and for the irradiation of other items.

AGENCY NOTE: Possession of a teletherapy unit that is out of service and in storage only does not mean the primary radioactive material use category is the teletherapy category described in 208B. Such licensees should review the other categories to determine their primary radioactive

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material use category. If this is the only material possessed under a specific license, then see category 212A.

- 208C. Medical/Veterinary Use – licenses for diagnostic and/or therapeutic human or veterinary use of radioactive material (i.e., 32 Ill. Adm. Code 335.5010 and/or 335.7010).
- 208D. Diagnostic Use Only – licenses restricted to only the diagnostic human or veterinary use of radioactive material for uptake, dilution, excretion, imaging or localization studies, sealed sources for diagnosis; and in vitro kits (i.e., 32 Ill. Adm. Code 335.4010), except as specified in 32 Ill. Adm. Code 330.220(eƒ).
- 208E. Limited Medical/Veterinary Use – licenses restricted to only the human or veterinary use of radioactive material for uptake, dilution and excretion studies (i.e., 32 Ill. Adm. Code 335.3010).
- 208F. Mobile Nuclear Medicine – licenses authorizing the receipt, possession and use of radioactive material for diagnostic or therapeutic human or veterinary use at temporary jobsites.

AGENCY NOTE: Licensees wishing to establish mobile medical services involving High Dose Rate Remote Afterloaders for therapeutic use in humans or animals shall be licensed under Category 208B.

GENERAL LICENSES

- 209A. Persons with Prepackaged Units for In Vitro Testing – persons who receive, acquire, possess or use prepackaged units for in vitro clinical or laboratory testing pursuant to the general license provided by 32 Ill. Adm. Code 330.220(eƒ)(1).
- AGENCY NOTE: Prepackaged units may be known as in vitro kits or RIA kits.
- 209B. Persons with Generally Licensed Devices – persons required to register with the Agency pursuant to 32 Ill. Adm. Code 330.220(aƒ)(4).

SOURCE MATERIAL

- 210A. Possession and Use of Source Material (as defined in 32 Ill. Adm. Code 310.20) and Byproduct Material (as defined in 32 Ill. Adm. Code 332.20)

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– licenses for possession and use of source material in recovery operations such as milling, in-site leaching, heap-leaching, ore buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations as well as licenses authorizing the possession and maintenance of a facility in a standby mode.

- 210B. Possession and Use of Source Material (as defined in 32 Ill. Adm. Code 310.20) – licenses for possession and use of source material that require a specific radioactive materials license. This does not include licenses authorizing manufacture and distribution of source material, nor does it include specific licensees authorizing source material used for shielding or source material authorized for use in manufacturing operations as described in Material Use Categories 201A, B and C of this Section.

WASTE DISPOSAL AND TREATMENT FACILITIES

- 211A. Low-Level Radioactive Waste Disposal Facilities – licenses issued pursuant to 32 Ill. Adm. Code 601 specifically authorizing the disposal of low-level radioactive waste away from the point of generation.
- 211B. Low-Level Radioactive Waste Treatment Facilities – licenses specifically authorizing the receipt of low-level radioactive waste material from other persons for treatment away from the point of generation, and transfer to a person authorized to receive or dispose of the material.
- 211C. Centralized Low-Level Radioactive Waste Storage Facilities – licenses specifically authorizing the receipt of low-level radioactive waste material from other persons for storage away from the point of generation, and transfer to a person authorized to receive or dispose of the material.
- 211D. Other Low-Level Radioactive Waste – licenses authorizing other methodologies for disposal of low-level radioactive waste.

OTHER

- 212A. Storage Only – licenses authorizing storage only of radioactive material, but does not include facilities described as Centralized Low-Level Radioactive Waste Storage Facilities.

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- 212B. Possession Incident to Exempt Distribution – licenses authorizing possession, receipt, storage and repackaging of byproduct radioactive material for eventual distribution to persons exempt under a specific license issued by the U.S. Nuclear Regulatory Commission.
- AGENCY NOTE: The U.S. Nuclear Regulatory Commission maintains sole authority to issue licenses authorizing distribution of exempt quantities of byproduct radioactive material. However, those licenses do not authorize storage of the material at facilities in Illinois, therefore, a separate license must be obtained from the Agency for possession of the material.
- 212C. Other – all other specific radioactive material licenses not specified elsewhere in this Appendix.
- 212D. Reciprocity for Exhibition and Demonstration Only – licenses authorizing only exhibition or demonstration of devices for a period of not greater than 180 days in any 12-month period.
- 212E. Sealed Source and Device Evaluation Maintenance Fee – a fee per active evaluation sheet maintained by the Agency excluding custom sealed source and device evaluation sheets.

(Source: Amended at 39 Ill. Reg. _____, effective _____)