



PROPOSED GENERAL LICENSE RULE CHANGE

To: Companies Possessing Gauging Devices Under a General License

From: Applied Health Physics, Inc.

Re: Proposed Restriction on Devices Containing Radioactive Sources

The United States Nuclear Regulatory Commission published a proposed rule change in the Federal Register Volume 74, No. 147 on August 3, 2009 and clarified the information in an August 5, 2009 newsletter. The proposed change would limit the amount of radioactive material currently authorized for distribution and possession under general license. This change, if legislated, will require any facility possessing gauging devices that contain in excess of one-tenth of the Category 3 threshold as established by the International Atomic Energy Agency (IAEA) to apply for a specific materials license. Examples of those potentially affected would include:

- Devices containing in excess of 160 millicuries of Am-241
- Devices containing in excess of 270 millicuries of Cs-137
- Devices containing in excess of 81 millicuries of Co-60

Comments on this topic may be mailed to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff. They may be e-mailed to: rulemaking.comments@nrc.gov or submitted via the Federal e-Rulemaking Portal at <http://www.regulations.gov> under Docket ID NRC-2008-0272.

Comments may also be faxed to the Secretary at 301-415-1101, or hand-delivered to 11555 Rockville Pike, Rockville, Md., between 7:30 a.m. and 4:15 p.m. on federal workdays.

Applied Health Physics, Inc. will monitor these events and provide updates on our website.

AHP



NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

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August 5, 2009

NRC PROPOSES STRONGER OVERSIGHT OF RADIOACTIVE MATERIALS

The Nuclear Regulatory Commission is proposing to strengthen oversight of radioactive materials by limiting the amount of radioactive material allowed in generally licensed devices.

“I believe this proposed rule is a positive step forward in increasing the accountability of these materials,” NRC Chairman Gregory B. Jaczko said. “I look forward to receiving input from the public on the agency’s proposal.”

The proposed rule would require owners of approximately 1,800 devices, an estimated 1,400 general licensees nationwide, to apply for specific licenses for the devices. This change applies primarily to fixed industrial gauges.

Requiring specific licenses for such devices would improve the safety, security and control over the gauges by bringing them under increased regulation, making it harder to accumulate a risk-significant amount of radioactive material or to procure a device through subterfuge.

The proposed rule was published Aug. 3 in the *Federal Register* for public comment, and is available online here: <http://edocket.access.gpo.gov/2009/pdf/E9-18438.pdf>.

Generally licensed devices typically contain radioactive material in a shielded, sealed housing. Their design includes inherent radiation safety features so the device may be safely used by someone with no radiation training or experience. Examples include gas chromatographs used in chemical analysis, static eliminators, ice detection devices and certain *in vitro* kits used in clinical or laboratory testing. Owners of such devices must fulfill certain recordkeeping requirements, but because of the built-in safety features, they do not have to apply to the NRC or a state regulatory agency for a specific license to possess or use the radioactive material.

The devices that would be affected by the proposed rule fall into Category 3 or the upper limits of Category 4 of the International Atomic Energy Agency’s (IAEA’s) categorization of radioactive sources. The U.S. government considers Category 1 and Category 2 sources to be the

most sensitive from a security standpoint. While sources in lower categories are considered less sensitive, the NRC is concerned that a small number of Category 3 or certain Category 4 sources together could be equivalent to a Category 2 amount of radioactive material.

The proposed rule would require specific licenses for devices containing radioactive material equal to or greater than 1/10th of the IAEA's Category 3 level. This requirement would improve NRC monitoring of the location and use of radioactive materials of higher activity and enhance the accountability and control of such devices. The more stringent requirements of the specific licensing process would minimize the potential for aggregation of radioactive materials to quantities of concern, thereby enhancing the NRC's ability to protect public health and safety. The proposed rule would also clarify the applicable requirements when a device authorized under a general license is instead held under a specific license.

For more information on the proposed rule, contact NRC staff member Solomon Sahle by phone at 301-415-3781 or via e-mail at solomon.sahle@nrc.gov.

Comments on the changes will be accepted through Oct. 19. Comments may be mailed to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff. They may be e-mailed to: rulemaking.comments@nrc.gov or submitted via the Federal e-Rulemaking Portal at <http://www.regulations.gov> under Docket ID NRC-2008-0272. Comments may also be faxed to the Secretary at 301-415-1101, or hand-delivered to 11555 Rockville Pike, Rockville, Md., between 7:30 a.m. and 4:15 p.m. on federal workdays.

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III. Discussion of Proposed Amendments by Section

10 CFR 31.5(a) General Domestic Licenses for Byproduct Material

The proposed rule would amend 10 CFR 31.5(a) to limit the quantity of byproduct material in generally licensed devices to below 1/10 of the IAEA's

Category 3 threshold, for the isotopes listed in Appendix E to 10 CFR Part 20. Licensees who possess devices containing byproduct material meeting or exceeding these thresholds would be required to become specifically licensed, and would become subject to all applicable regulations. Devices containing byproduct material below

these thresholds would continue to be generally licensed.

The values corresponding to Category 3 and 1/10 of Category 3 (or 1/100 of Category 2) in Appendix E to 10 CFR Part 20 for byproduct material radionuclides are provided here as information along with the notes to the table.

Radioactive material	Category 3 (TBq)	Category 3 (Ci)	1/10 Category 3 (TBq)	1/10 Category 3 (Ci)
Actinium-227	0.02	0.54	0.002	0.054
Americium-241	0.06	1.6	0.006	0.16
Americium-241/Be	0.06	1.6	0.006	0.16
Californium-252	0.02	0.54	0.002	0.054
Cobalt-60	0.03	0.81	0.003	0.081
Curium-244	0.05	1.4	0.005	0.14
Cesium-137	0.1	2.7	0.01	0.27
Gadolinium-153	1	27	0.1	2.7
Iridium-192	0.08	2.2	0.008	0.22
Plutonium-238	N/A	N/A	N/A	N/A
Plutonium-239/Be	N/A	N/A	N/A	N/A
Polonium-210	0.06	1.6	0.006	0.16
Promethium-147	40	1100	4	110
Radium-226	0.04	1.1	0.004	0.11
Selenium-75	0.2	5.4	0.02	0.54
Strontium-90	1.0	27	0.1	2.7
Thorium-228	N/A	N/A	N/A	N/A
Thorium-229	N/A	N/A	N/A	N/A
Thulium-170	20	540	2	54
Ytterbium-169	0.3	8.1	0.03	0.81

Note: N/A means "not applicable" because Plutonium-238 and Plutonium-239/Be are not byproduct material but are special nuclear material. Thorium-228 and Thorium-229 are source material.

10 CFR 31.5(b)(3)

A clarification concerning the applicable requirements for devices authorized for use under 10 CFR 31.5 but held under specific license would be added.

IV. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA) of 1954, as amended, the Commission is proposing to amend 10 CFR Part 31 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

V. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the Federal Register on September 3, 1997 (62 FR 46517), the proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC's requirements. The NRC staff analyzed the proposed rule in accordance with the procedure established in Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive

5.9, "Adequacy and Compatibility of Agreement State Programs."

As a result of the amendments to 10 CFR 31.5(a) and new section (b)(3), these sections would now be designated as Compatibility Category C. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt these essential objectives. After considering the issues associated with the compatibility requirements for 10 CFR 31.5(c)(13)(i), this section would now be designated as Compatibility Category C. After considering the issues associated with the compatibility requirements for 10 CFR 31.6, this section would now be designated as Compatibility Category C. For the reasons provided in Section B of this document, the NRC is proposing to designate 10 CFR 31.5(a), (b)(3), (c)(13)(i), and 31.6 as Compatibility Category C and, by so doing, Agreement States would have flexibility to adopt additional requirements, based on their circumstances and needs, if necessary. This would also allow Agreement States

the flexibility to adopt additional requirements for tracking the movement of service providers and the location of generally licensed devices. Designating 10 CFR 31.5(a) and 31.6 as Compatibility Category C would address the issues and concerns raised by the OAS in their June 2005, petition for rulemaking. Designating 10 CFR 31.5(c)(13)(i) as Compatibility Category C the NRC would address the issues and concerns raised by the State of Florida in their June 2005 request as part of the petition. Considering these issues in this rulemaking action closes the entire petition.

VI. Plain Language

The Presidential Memorandum "Plain Language in Government Writing" published June 10, 1998 (63 FR 31883), directed that the Government's documents be in clear and accessible language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the ADDRESSES heading.

VII. Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards