



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
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(FSME-12-082, October, Program, GLDs)

October 12, 2012

ALL AGREEMENT STATES

**NRC NOTIFICATION OF SECURITY REQUIREMENTS FOR GENERALLY LICENSED DEVICES CONTAINING HIGH ACTIVITY SOURCES (FSME-12-082)**

**Purpose:** To inform the Agreement States that security requirements are applicable for generally licensed devices (GLDs) which contain sources with activity levels in International Atomic Energy Agency (IAEA) Category 2 and above quantities of radioactive material, which the Nuclear Regulatory Commission (NRC) considers to be risk-significant and, therefore, warrant protection.

**Background:** GLDs must be registered for use under 10 CFR 30.32(g) and the registration is performed, through a safety evaluation of the device, under 10 CFR 32.51 or equivalent Agreement State regulations. The regulations do not specify the maximum activity level that GLDs may contain; the regulations use other performance-based criteria. An audit conducted by the Office of the NRC Inspector General ("Audit of the NRC's Issuance of General Licenses," Report No. OIG-12-A-14, dated June 28, 2012) noted that GLDs are allowed to be registered containing sources with activity levels of IAEA Category 2 or higher. The NRC or Agreement State increased controls security requirements are applicable to sealed sources and devices with such activity levels.

**Discussion:** The guidance, used by the staff of the NRC and the Agreement States, for the conduct of the safety evaluation is NUREG-1556, Vol. 3, Rev. 1, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Registration." The current edition of the guidance document does not address the issue of security requirements for high activity GLDs. The NRC is in the process of updating the guidance document, and we have developed direction regarding this issue for the new edition. Until the update is published, we are providing, for your use, the text of the additional guidance that we intend to include in the update of NUREG-1556, Vol. 3 (see Enclosure).

No action or response on part of the Agreements States is requested or required. The Agreement States may choose to adopt and use the guidance in the Enclosure.

If you have any questions regarding this communication, please contact me at (301) 415-3340 or my staff named below.

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**/RA/**

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## ENCLOSURE

### **Security Requirements for Devices Used under the General License in 10 CFR 31.5**

[New addition to guidance document NUREG-1556, Vol. 3, Section 4.3]

For generally licensed products containing certain byproduct materials in quantities of concern, the reviewer must be aware that the NRC or Agreement State increased controls security requirements are also applicable. The reviewer should include a Reviewer's Note in the device registration regarding the security requirements and should also coordinate the issuance of the registration certificate with the NRC or Agreement State licensing staff.

The security requirements apply to the use and transport of International Atomic Energy Agency (IAEA) Category 2 and above quantities of radioactive material, which the NRC considers to be risk-significant and, therefore, warrant additional protection. Category 2 and above thresholds are based on those established in the IAEA Code of Conduct on the Safety and Security of Radioactive Sources. The current security requirements are listed in the "Order Imposing Increased Controls," published in the Federal Register on December 1, 2005 (70 FR 72128), and in the "Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials" (Fingerprinting Order), published in the Federal Register on December 13, 2007 (72 FR 70901). A proposed rule on Physical Protection of Byproduct Material, "Part 37 – Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," was published in the Federal Register on June 15, 2010 (75 FR 33901).

The quantities of concern include security requirements for the use and transport of Category 2 and above quantities of radioactive material. To facilitate the determination regarding the applicability of the increased controls security requirements, the table below establishes the radionuclides and associated thresholds for Category 2 quantities of radioactive material, in addition to the methodology for calculating the sum of fractions for evaluating combinations of multiple radionuclides.

(cont'd)

Radioactive Material	IAEA Category 2 Threshold <sup>1</sup>	
	Terabecquerels (TBq)	Curies (Ci)
Americium-241	0.6	16.2
Americium-241/Beryllium	0.6	16.2
Californium-252	0.2	5.40
Curium-244	0.5	13.5
Cobalt-60	0.3	8.10
Cesium-137	1	27.0
Gadolinium-153	10.0	270
Iridium-192	0.8	21.6
Plutonium-238	0.6	16.2
Plutonium-239/Beryllium	0.6	16.2
Promethium-147	400	10,800
Radium-226	0.4	10.8
Selenium-75	2.0	54.0
Strontium-90 (Yttrium-90)	10.0	270
Thulium-170	200	5,400
Ytterbium-169	3	81.0

<sup>1</sup>Calculations Concerning Multiple Sources or Multiple Radionuclides

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a facility or activity meets or exceeds the threshold and is thus subject to the physical protection requirements of this part.

I. If multiple sources and/or multiple radionuclides are present in a facility or activity, the sum of the ratios of the activity of each of the radionuclides must be determined to verify the facility or activity is less than the category 1 or category 2 thresholds of Table 1, as appropriate. Otherwise, if the calculated sum of the ratio, using the following equation, is greater than or equal to 1.0, then the facility or activity meets or exceeds the thresholds of Table 1, and the applicable physical provisions of this part apply.

II. Use the equation below to calculate the sum of the ratios by inserting the actual activity of the applicable radionuclides from Table 1 or of the individual sources (of the same radionuclides from Table 1) in the numerator of the equation and the corresponding threshold activity from the Table 1 in the denominator of the equation. Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

$R_1$  = activity for radionuclides or source number 1

$R_2$  = activity for radionuclides or source number 2

$R_N$  = activity for radionuclides or source number n

$AR_1$  = activity threshold for radionuclides or source number 1

$AR_2$  = activity threshold for radionuclides or source number 2

$AR_N$  = activity threshold for radionuclides or source number n

$$\sum_1^n \left[ \frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \frac{R_n}{AR_n} \right] \geq 1.0$$