

**THE APPLICATION OF THE GRADED APPROACH TO THE
REGULATION OF RADIOACTIVE SOURCES IN THE
UNITED STATES**

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Development and oversight of regulations that account for the overall risk posed by radioactive materials requires integration of safety and security programs. Implementing a graded approach to both safety and security allows the U.S. Nuclear Regulatory Commission (NRC), along with our Agreement State partners, to ensure adequate protection without unnecessary burden. This graded approach allows the United States (U.S.) to realize and take full advantage of the benefits of the various uses of radioactive materials, while ensuring consistent and sustainable safety, security, and control of radioactive sources – from allowing exemptions from regulations for specific items, through sources and uses for which prudent management practices or existing safety requirements are sufficient, to the highest activity sources and practices that deserve the tightest control.

The U.S. framework relies on various safety - including operational experience - and security analyses - including threat, vulnerability, and consequence - to determine the appropriate framework and requirements for each circumstance. These analyses form the basis for the graded requirements applicable to all civilian radioactive and nuclear material in the U.S. For example, sources that present minimal to negligible hazard, such as smoke detectors and gunsights, are exempt from licensing entirely for the end-user, while still other sources, such as those in robust devices, are subject to registration and notifications of transfers to the regulatory agency.

Although the basic radiation protection standards and licensing standards for all licensee types can be found in Title 10 *Code of Federal Regulations* (10 CFR) Part 20 and Part 30, respectively, additional requirements have been developed and are enforced for users based upon both use type and the activity of the radioactive source or sources. As an example, for the majority of licensed civilian radioactive and nuclear material in the U.S. the physical protection measures can be found in 10 CFR Part 20, in paragraphs 1801 and 1802. Although, in short, these paragraphs state only that licensees must secure their material while in storage and that it must be under constant surveillance while in use – they do not specify exactly what means a licensee must use to accomplish those objectives. Similarly, while the radiation protection and licensing requirements provide dose limits and activity levels as a basis for things such as transport labeling and financial assurance for decommissioning, the regulations are, again, generally performance-based and do not specify exactly what means a licensee must use to accomplish these objectives. Thus, licensees must develop processes and procedures that are subject to inspection, to meet all the applicable objectives and regulations.

For other licensed material, and for specific modalities of use, additional (not replacement) requirements apply. An example of this is a well logging licensee who

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possesses a category 3 americium-241/beryllium source. This licensee must comply with the safety and security requirements in 10 CFR Part 20 that includes the establishment and maintenance of a radiation protection program that will limit occupational and public exposures to radiation to below regulatory limits. Additionally, the licensee must comply with requirements in 10 CFR Part 30 to maintain their license in good standing including allowing for regulatory approval to amend a license. For this licensee type compliance with further requirements in 10 CFR Part 39 that are specific to well logging operations also apply. These requirements include additional labeling, security, and transport requirements as well as operational and administrative requirements including for operating from field stations or temporary jobsites.

Another example is that of a radiopharmacy who also must comply with the same safety, security, and licensing requirements in 10 CFR Parts 20 and 30, but due to their special operational methods, must also comply with the additional requirements for a distributor of radioactive materials in 10 CFR Part 32 as well as comply with the training requirements for a nuclear pharmacist in 10 CFR Part 35. Notable in this example is that the nuclear pharmacist, in order to be designated on the radioactive materials license must have successfully completed an accredited pharmacy educational program and be a licensed pharmacist – neither the accreditation nor the pharmacy license is overseen by the NRC, but are examples of cooperation across professional specialties and regulatory programs.

For sources or aggregated quantities of radioactive material that the U.S. has determined to be risk-significant, that is that meet or exceed the category 2 threshold, further requirements of 10 CFR Part 37 must be implemented by the licensee to ensure additional physical protection. An example of this situation is an industrial radiography licensee who possesses a camera (or multiple cameras) containing a category 2 iridium-192 source who must comply with 10 CFR Parts 20 and 30 (like the previous examples), the additional specific safety requirements for radiography in 10 CFR Part 34 such as personnel wearing alarming dosimetry, and further security requirements in 10 CFR Part 37 such as providing extra barriers for their mobile source(s).

Radioactive sources also pose extremely varied potential detriment to human health. The NRC's graded approach also takes this into consideration by requiring more extensive, and sometimes more prescriptive, requirements for radioactive sources or activities that pose higher risk of injury. At extreme ends of this spectrum are the case of a residential smoke detector that contains a very low activity americium-241 source and a panoramic irradiator that can utilize a very high activity of cobalt-60 for sterilization purposes. The smoke detector, while it's manufactured and distributed by a licensed entity, is destined for possession, use, and ultimately disposal, by a member of the public. This person has no requirements imposed on them because the possession and use is of a product that is exempt from licensing. Contrasting that situation with the panoramic irradiator that has robust safety and security measures applicable to its operation, including for construction and functioning that will prevent a person from entering the irradiation vault but will also fail-safe and shield the radioactive sources if a person does manage to enter during an irradiation cycle.

These examples demonstrate the commitment to maintaining adequate protection of workers, the public, the environment, and the security of the U.S., but also demonstrate a recognition of the differences among the large population of users of radioactive and nuclear material within the U.S.

The NRC has conducted multiple efforts to evaluate this framework in the past 3 years and continues to develop guidance and revise policies to ensure that modern technology is accounted for in the regulatory framework. To ensure that security

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measures are adequate the NRC has performed a review of the security framework for Category 1 and 2 quantities of radioactive materials¹, and later performed a reevaluation of the security and licensing framework for Category 3 radioactive sources². Technology and use-specific evaluations with a safety focus have also been conducted to ensure that requirements that were often drafted decades ago can accommodate current technology and current industry and public need. For example, in 2016 the NRC evaluated the use of combination dosimetry devices for use in radiographic operations. The evaluation and decision to allow the use of such devices in the U.S. to comply with existing requirements was provided to licensees.³ Similarly, concern with release of patients who have undergone treatment with radiopharmaceuticals, considering both healthcare practices in the U.S. as well as doses that may be received by members of the public or the patient's family and friends, has also generated an evaluation by the NRC into the patient release criteria. This activity was submitted to the NRC Commission for final direction after receiving a high degree of interest from a wide variety of sectors including the healthcare profession, patient advocacy groups, and insurance/Federal health agencies.⁴

The U.S. regulatory framework, designed to rely on a graded and integrated safety and security approach, changes deliberately with careful consideration and allows the population of the U.S. to realize the full potential positive uses of the radioactive sources, while also protecting the public health and safety, common defense and security, and the environment from the potential harmful effects of radiation.

¹ See "10 CFR Part 37 Program Review" on NRC's public website at <https://www.nrc.gov/security/byproduct/10-cfr-part-37-program-review.html>

² See "Category 3 Source Security and Accountability Re-Evaluation" on NRC's public website at <https://www.nrc.gov/security/byproduct/category-3-source-security-accountability-reevaluation.html>

³ See "NRC Regulatory Issue Summary 2017-06: NRC Policy on Use of Combination Dosimetry Devices During Industrial Radiographic Operations"

⁴ See "SECY-18-0015: Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release After Radioisotope Therapy"