

Addressing Sealed Source Concerns Through the License Inspection Process

The risk significant radioactive sealed sources generally fall into the International Atomic Energy Agency (IAEA) Categories 1, 2 and 3.¹ All Category 1 and 2 sources are specifically licensed, meaning that a regulatory agency, such as the US Nuclear Regulatory Commission (NRC) or an Agreement State program, has evaluated the possessor and intended use of the radioactive material and determined that the possessor has demonstrated the necessary qualifications to safely utilize the radioactive material. Some sealed sources are licensed through a general license. NRC's regulations provide a general license for the use of byproduct material contained in certain products. This general license allows certain persons to receive and use a device containing byproduct material if the device has been manufactured and distributed in accordance with a specific license issued by the NRC or by an Agreement State.²

Through existing NRC and Agreement State regulations, specific licensees are inspected on a routine periodic basis. Depending on the specific licensee, the inspection frequency typically ranges from one year to five years. During the inspection process the inspector can discuss with the licensee their inventory of sources in long-term storage. The inspector can question the licensee on their storage procedures, inventory verification, security protocols, and justification for continued storage.

The NRC has developed several documents related to their inspection process. Agreement State Programs use these or similar procedures. They include:

- NRC Inspection Manual, Inspection Manual Chapter 2800, Materials Inspection Program
- NRC BR-0334 Materials Inspection & Licensing Handbook Best Practices
- NRC Inspection Manual Inspection Procedure 87121 Industrial Radiography Programs
- NRC Inspection Manual Inspection Procedure 87123 Well Logging Programs
- NRC Inspection Manual Inspection Procedure 87124 Fixed and Portable Gauge Programs

¹ International Atomic Energy Agency (IAEA) *Code of Conduct* and IAEA *Safety Guide #RS-G-1.9, "Categorization of Radioactive Sources"* establishes sealed sources Categories 1 through 5, with Category 1 being the greatest risk and Category 5 being the lowest risk. Categories 1, 2, and 3 are all classified as "dangerous" sources.

² Taken from the US NRC website: <https://www.nrc.gov/materials/miau/general-use.html>

- NRC Inspection Manual Inspection Procedure 87126 Industrial/Academic/Research Programs
- NRC Inspection Manual Inspection Procedure 87132 Brachytherapy Programs
- NRC Inspection Manual Inspection Procedure 87133 Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs
- NRC Inspection Manual Inspection Procedure 87132 Medical Broad-Scope Programs

Inspection Manual Chapter 2800, Materials Inspection Program, details the common elements for inspections, which include:

1. Entrance Meeting
2. Review of Open Items
3. General Overview
4. Observations of Actual Facilities and Licensed Activities
5. Interviews with Licensee Personnel
6. Independent and Confirmatory Measurements
7. Record Review
8. Special License Conditions
9. Communication of Findings
10. Exit Meeting

The Best Practices handbook provides easy to understand advice based on the experience of NRC and Agreement State inspectors. The Entrance and Exit meetings are the prime opportunity for the inspector to convey information directly to licensee management.

The Entrance Meeting is used to inform licensee management of the schedule and activities and to make them aware that an Exit Meeting will be conducted with the most senior available management representative at the end of the inspection. The Exit Meeting is where the findings of the inspection are discussed with licensee management. This is also where concerns about the extended storage of sealed sources can be discussed.

A common thread through the Inspection Procedures identified above is focusing on the physical inventory of sealed sources and devices. The inspector, through interviews and review of records, should determine that the inventory of sealed sources is properly accounted for. The Best Practices manual advise: “Trust the licensee to provide you with accurate information; verify the accuracy of selected information you obtain from the licensee.”³

The best way to verify the accuracy of the information provided by the licensee is to visually observe the sealed source or device. Devices containing sealed sources that are installed within a manufacturing facility may be more difficult than sealed sources stored in a safe. However, an effort should be made to verify the presence of devices, even if it is only a representative sample. Any discrepancies in the inventory should be noted and discussed with the licensee management.

³ US NRC BR-0334 Materials Inspection & Licensing Handbook Best Practices, pg.10.

Inspections are closed out onsite during an exit interview with licensee management personnel to discuss the findings of the inspection. During this time the inspector can apprise management of any concerns with the sealed sources or devices in long-term storage, provide recommendations for disposition, and identify the potential liabilities associated with continued storage or loss of control. The inspector can provide the licensee management with appropriate informational resources to help guide them with the proper dispositioning of disused sealed sources and devices.

The DSWG endorses the concept of using the inspection process to educate the licensee (especially management) of the potential concerns associated with long-term storage of disused sources. Given the guidance in the inspection procedures, any additional effort for the inspector is minimal. Implementing this recommendation requires no changes to regulations. Inspectors generally have wide latitude to ask questions or request information from licensees, and for the most part are already collecting this information.

The steps in promoting this recommendation would start with the Organization of Agreement States (OAS) and work its way to the NRC. The OAS is the representative organization for the 39 Agreement State programs. Meetings should be held with the appropriate OAS working group to discuss the merit of using the inspection process for educating licensees about the concerns associated with long-term storage. The desired outcome would be to develop inspection guidance that specifically addressed the long-term storage of disused sources and an information package that would assist licensees in properly dispositioning unwanted sealed sources.