

APPENDIX H

Opening Packages Containing Radioactive Material and Return of Radioactive Waste and Unused Dosages

During normal working hours, packages containing radioactive materials will be monitored as soon as practicable after receipt (not to exceed 3 hours). Packages received after normal working hours will be monitored within 3 hours from the beginning of the next working day, as required by subsection 64E-5.327(3), Florida Administrative Code, (F.A.C.).

OPENING PACKAGES CONTAINING SPECIFICALLY LICENSED MATERIAL

1. Put on gloves to prevent hand contamination.
2. Check the survey meter for proper operation with a dedicated check source.
3. Measure the exposure rate of the package at one meter (3.3 feet) and then measure the exposure rate at the surface of the package. Record the survey results and compare to the limits on the below listed DOT Shipping Label Chart.

If survey measurements exceed the values listed on the chart, stop the procedure and immediately notify the radiation safety officer (RSO).

4. Visually inspect the package for any sign of damage (e.g., wet or crushed).
If damage is noted, stop the procedure and notify the RSO.

DOT Shipping Label Chart

Label Category	Surface Level (mR/hr)	Transportation Index (TI) at 1 meter (mR/hr)
White I	0-0.5	background
Yellow II	0.5 - 50	0.1 - 1.0
Yellow III	50 - 200	1.0 - 10

5. Open the package with the following precautionary steps:
 - A. Remove the packing slip.
 - B. Open the outer package following the supplier's instructions when provided.
 - C. Open the inner package and verify that the contents agree with the packing slip.
 - D. Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
 - E. If anything is other than expected, *stop and notify the RSO.*
6. Wipe the external surface of the final source container and remove the wipe sample to a low background area. Survey the wipe with the G-M survey meter. If the meter indicates a reading above background, *stop the procedure and notify the RSO.*
7. Check the user request to ensure the material received is the material that was ordered.

8. Monitor the packing material and the empty packages for contamination with a G-M survey meter before discarding.
 - A. If contaminated, treat this material as radioactive waste.
 - B. If not contaminated, remove or obliterate the radiation labels before discarding in non-radioactive trash.
9. Records of package opening survey results are maintained for 3 years as specified in section 64E-5.336, F.A.C.
10. Section 64E-5.327, F.A.C., allows certain exemptions from package contamination surveys for radioactive material in the form of gas or special form.

“Special form” means radioactive material that satisfies all of the following conditions:

 - (a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
 - (b) The piece or capsule has at least one dimension not less than 5 millimeters; and
 - (c) It satisfies the test requirements of 49 CFR, section 173.469. Special Form encapsulations designed in accordance with the requirements of section 49 CFR section 173.389 in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. Special form encapsulations either designed or constructed after June 30, 1985, must meet the requirements of this part.

RETURN OF WASTE AND UNUSED DOSAGES-LIMITED QUANTITIES

Under the provision of 49 CFR section 173.421, packages of radioactive material returned to pharmacies are labeled as “Limited Quantity Shipments.” Limited Quantity is defined as a “maximum amount of a hazardous material for which there is a specific labeling or packaging exception.” 49 CFR section 173.421 states that if a package meets the following requirements it is exempted from the specifications of packaging, marking, and labeling.

1. The amount of radioactivity in the package does not exceed a specified amount. (A table is attached specifying the limit for each commonly used radiopharmaceutical.)
2. The radiation level at any point on the external surface of the package does not exceed 0.5 millirem per hour.
3. The non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed 6600 dpm/300 cm². (49 CFR section 173.443[A][2]).

LIMITED SHIPMENT QUANTITIES FOR COMMONLY USED RADIODIAGNOSTIC AND SEALED SOURCES

Radionuclide	Liquids (mCi)	Sealed Sources (mCi)
Ba-133	-	81.0
Co-57	27.0	27.0
Co-60	-	11.0
Cr-51	81.0	-
Cs-137	-	54.0
F-18	1.6	-
Ga-67	8.1	-
Gd-153	-	270.0
Ge-68	-	14.0
I-123	8.1	81.0 (solid form)
I-125	8.1	540.0
I-131	1.9	-
In-111	8.1	-
Mo-99	1.6	-
P-32	1.4	-
Pd-103	-	1100.0
Sm-153	1.6	-
Sr-89	1.6	-
Se-75	8.1	-
Tc-99m	11.0	-
Tl-201	11.0	-
Xe-133 gas (uncompressed, $A_2 \times 10^{-3}$)	270.0	-
Y-90	0.81	-

The above values have been calculated using information from 49 CFR section 173.423, Table 7, and 49 CFR 173.435, Table of A_1 and A_2 Values for Radionuclides. When shipping more than one type of radioactive material in the same package, the limit on the radioactivity that may be shipped is determined by the lowest curie quantity assigned for items shipped.

Example: If Tc-99m and Se-75 were being shipped in same package, only 8.1 mCi of total activity could be shipped.

Procedures

1. Ensure that the radioactive waste being returned does not exceed the specified limits for "Limited Quantity Shipments."
2. Determine that the radiation level at any point on the surface of the package does not exceed 0.5 mR/hr by surveying the package prior to shipment.
3. Determine that the non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR subsection 173.443(a), for example, 22 dpm/cm² when wiped over a 300 cm² area. A wipe of the package will be performed, analyzed and evaluated in the dose calibrator for activity. The activity will be the number of microcuries multiplied by 2.22×10^6 to convert activity in microcuries to disintegration per minute.
4. If the package does not exceed the limits in 1, 2 and 3, the package may be shipped as a limited quantity shipment. The outside of the inner package or, if there is no inner package, the outside of the packaging itself bears the marking "Radioactive."

5. Outside of limited quantity package must be marked with UN identification number preceded by the letters UN (i.e. UN2910).
6. If the package exceeds the limited shipment quantity, surface dose rate or removable contamination in excess of 2200 dpm/100cm², the package may not be shipped as limited quantities and will be held at the facility.

RETURN OF WASTE AND UNUSED DOSAGES-OTHER THAN LIMITED QUANTITIES

Procedures

1. Ensure that the radioactive waste being returned does not exceed the specified A₁ for special form and A₂ for normal form material as described in Appendix A to Part 71, Florida Administrative Code (F.A.C.), for Type A packages.
2. The radioactive material will be placed into appropriate shielding.
3. The shielded radioactive material will be placed in a DOT Type A shipping container. The container will also include absorbent material sufficient to absorb the liquid contents of the container.
4. A copy of the Type A container testing methods and results for each Type A package in use will be on file, for at least one year after the latest shipment.
5. The appropriate label will be applied to the outside of the box. Determination of the transport index is accomplished by placing the package one meter from a calibrated instrument in mR/hr. Determination of the radioactive White I, Yellow II, or Yellow III, is accomplished by taking surface readings of the package as well as the T.I. The following criteria will used to determine the proper labeling:

DOT Shipping Label Chart

Label Category	Surface Level (mR/hr)	Transportation Index (TI) at 1 meter (mR/hr)
White I	0 - 0.5	background
Yellow II	0.5 - 50	0.1 - 1.0
Yellow III	50 - 200	1.0 - 10

6. A wipe test shall be performed over 300 cm² external package area to ascertain that the container has removable contamination less than 6600 dpm/300 cm².
7. The package will be marked on the outside "USDOT 7A Type A" and "Radioactive Material." The package will be labeled on at least two sides of the package and near the proper shipping name marking.
8. The radioactive label will state the radionuclide or radionuclides, its chemical form, the quantity.
9. Each package will state the name and address of the pharmacy who will receive the package.
10. Shipping papers will be completed and the package will be transferred to the nuclear pharmacy.