

RECEIVING RADIOPHARMACEUTICALS
UPDATED: JULY 2007

CPT CODE: N/A

- Purpose:** To ensure safe handling procedures when receiving radiopharmaceuticals.
- Personnel:** Only personnel authorized by the UW-Safety department to handle radioactive material, and who have been properly trained in UWHC Nuclear Medicine procedures may receive radiopharmaceuticals.
- Delivery:** During normal Nuclear Pharmacy business hours (0600-1700 M-F), carriers will be instructed to enter UWHC through the 3rd floor entrance, and deliver the radiopharmaceutical directly to the Nuclear Pharmacy (Room E1/378). After hours, carriers must contact hospital security to gain entry to the Nuclear Pharmacy, and sign the "Radioactive Materials Receipt Log for After Hours Deliveries".
- Procedure for Opening Packages:** Within 3 hours of receipt of package during normal delivery hours, a package containing radiopharmaceuticals will be opened. The procedures in the NRC Model Procedure in Regulatory Guide 10.8, Appendix L [see attached] will be followed.
- Step 1: Check package with survey meter
 - At 1 meter: "Radioactive - White I" - N/A
"Radioactive - Yellow II" - ≤ 1 mR/hr
"Radioactive - Yellow III" - ≤ 10 mR/hr
 - At the surface: "Radioactive - White I" - ≤ 0.5 mR/hr
"Radioactive - Yellow II" - > 0.5 to ≤ 50 mR/hr
"Radioactive - Yellow III" - > 50 to ≤ 200 mR/hr
 - Step 2: Wipe test the package (300 cm³)
 - Count the wipe test in the Packard autogamma counter or the Capintec MCA/well counter
 - Step by step instructions for running the wipe test will be maintained in the Nuclear Pharmacy Operations Manual
 - Action level: 2,200 dpm/100 cm³
 - In the case of contamination, notify the vendor and the UW Radiation Safety Officer. A master list of vendors will be maintained and posted next to the phones in the Nuclear Pharmacy and Nuclear Pharmacist office.
 - Step 3: Open the package
 - Step 4: Assay the radiopharmaceutical and enter the information into the computer database
 - Information entered includes: time and date received, activity, concentration, calibration time and date, expiration time and date, drug cost, Prescription/Shipping Number.
 - Enter the survey and wipe tests results into the computer database
 - Step by step instructions for computer order entry will be maintained in the Nuclear Pharmacy Operations Manual.
 - Step 5: File paperwork
 - Paperwork is filed in vendor specific folders. Certain products are shipped by one vendor, but billed and filed by another vendor. A master list of radiopharmaceuticals and their preferred vendors will be maintained in the Nuclear Pharmacy Operations Manual.
 - Paperwork to be filed includes (stapled together): vendor packing list/prescription, bill of lading, survey and wipe test results.

Inventory: The computer software tracks all inventory including:

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- The amount ordered
- The amount received
- The amount in active inventory
- The amount used to compound other radiopharmaceuticals
- The amount administered
- The amount in waste

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APPENDIX L: Model Procedure for Safely Opening Packages Containing Radioactive Material

(See §§ 35.23, 30.51, 20.203(f)(4), and 20.205.)

You may use the following model procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2."

If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Say on your application, "We have developed a package opening procedure for your review that is appended as ATT 10.7," and append your package opening procedure.

MODEL PROCEDURE

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm².
2. For packages received under the specific license, the following procedure for opening each package will be followed:
 - a. Put on gloves to prevent hand contamination.
 - b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
 - c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see § 71.4 of 10 CFR Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See § 172.403 of 49 CFR Part 172.))
 - d. Open the package with the following precautionary steps:
 - (1) Remove the packing slip.
 - (2) Open the outer package following the supplier's instructions, if provided.
 - (3) Open the inner package and verify that the contents agree with the packing slip.
 - (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
 - (5) If anything is other than expected, stop and notify the RSO.
 - e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. [The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.] Take precautions against the potential spread of contamination.
 - f. Check the user request to ensure that the material received is the material that was ordered.
 - g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.
 - (1) If contaminated, treat this material as radioactive waste.

- (2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
 - h. Make a record of the receipt.
3. For packages received under the general license in § 31.11, the following procedure for opening each package will be followed:
- a. 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.
 - b. Check to ensure that the material received is the material that was ordered.

See Exhibit 12 for a sample record form you may want to use.