SHINE EU Therapeutics production facility material receipt and accountability procedure

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1 Purpose

The purpose of this procedure is to provide instruction for receipt and storage of radiological material consistent with the requirements described in [1], “SHINE EU Radiation Protection Program”.

2 Scope

The scope of this procedure pertains to the receipt of radioactive material, secure storage, and secure transport of radioactive materials

3 Responsibilities

Role	Responsibility
Radiation Protection Unit (RPU)	• Responsible for the overall implementation of the Radiation Protection Program. • Approves orders for the procurement of radioactive material. • Reports radiological incidents to the Nuclear Safety Authority (ANVS). • Ensures that receipt processes are properly performed, including the verification, surveying, opening, and inventorying of received radioactive material. • Evaluates damaged radioactive packages and carries out or oversees the performance of radiation/contamination surveys and decontamination operations if necessary. • Maintains an inventory of licensed materials. • Ensures that radioactive material is stored in a secure location. • Approves shipment of licensed material off site.
Radiation worker	Responsible for taking possession of packages containing radioactive material and transferring packages and shipping documents to a secure storage area.
Receiver	Must be a trained Radiation Worker (category A or B). Inspects labeling of received packages and identifies those packages containing radioactive material. Inspects incoming packages containing radioactive material for damage.

4 Procedure

4.1 General Requirements

1. The RPU shall approve orders for procurement of radioactive materials to ensure that requested material and quantities are authorized by the radioactive materials license and does not exceed the maximum possession limits.
2. Deliveries of radioactive materials shall be scheduled during SHINE standard business hours when trained staff will be available to receive the material. If deliveries are made after SHINE standard business hours, arrangements shall be made in advance and the RPU or designee will be notified.
3. The RPU shall be notified of the scheduled delivery date and time. Receivers shall be trained to perform the duties described in this procedure.
4. As needed, ANVS notification shall be made to: ANVS; 088-4890500

4.2 Material Receipt

- The receiver shall verify the package is intended for the facility.
- The receiver shall inspect labeling and shipping papers of materials received and identify radioactive material packages.
- The receiver shall immediately notify the RPU that an incoming radioactive material package has been received, with the actual activity based on the shipping documents.
- The receiver shall inspect the incoming radioactive material package for damage and for signs of leakage. If the package is damaged or appears to be damaged and/or shows signs of leakage, the receiver shall immediately notify the RPU of the actual or potential damage, inform the driver immediately, and hold the driver until completion of the survey. Survey the package to determine if there is any contamination. Document any individuals who may have come into contact with the package and any place the package may have been, and report to the RPU.
- The receiver shall transfer the package and shipping papers to a designated secure storage area and inform the RPU of the location of the package.
    - If the receiver does not have access to the secure storage, then the receiver notifies the RPU who will then place the package in secure material storage.
- As soon as practicable, but not later than three business hours after package receipt, the RPU shall perform the verification, surveying, opening, and documentation for inventory.
- For Type B packages received at the SHINE EU Therapeutics Facility, follow the applicable package certification handling requirements. The personnel responsible for opening Type B packages shall review and understand the handling requirements and opening instructions prior to opening the package.
- If with the quantity of radioactive material received, the total amount of radioactivity exceeds the license possession limit (max Re), the RPU shall immediately notify ANVS and the shipper and determine how and when the package will be returned.

- If removable radioactive surface contamination exceed the limits of Vbs article 1.1 or the external radiation levels as mentioned in the shipping documents, the RPU shall:
    - Carry out a contamination survey of the individuals and places that may have come into contact with the package and decontaminate them if necessary.
    - Immediately notify the final delivery carrier and ANVS.
- If acceptable, the radioactive material shall be stored in a secure location.

4.3 Inventory Control of Licensed Sources

- Physical inventories of the licensed calibration sources shall be performed every 6 months.
    - Identification of missing radioactive material shall be reported to the RPU immediately.

4.4 Inventory Control of Lutetium (Lu) and Ytterbium (Yb)

- Upon receipt of Lu and Yb, the amount received shall be verified (as indicated by the shipping documents) and compared to the maximum amount under the license while considering the amount that is already onsite.
- During use, the Lu and Yb will be kept in the processing glovebox, shielded process equipment, fume hood, or shielded Biosafety Cabinet areas, unless samples are taken for analysis by the HPGe or other instruments.
- After experimentation or processing, the Lu and Yb will be returned to storage or shipped, using appropriate shipping packaging, to be independently analyzed or processed by offsite customers.
- Inventory of the Lu and Yb will be done by keeping records of the amount of each isotope received, decay for each isotope, and each isotope shipped off site.
- Inventories of Lu and Yb shall be performed monthly when not in use, and weekly when in use.
- Missing Lu and/or Yb shall be reported to the RPU immediately.
- The inventory of Lu and Yb shall be updated as material is received on site or shipped off site.
- Whenever inventories of Lu and Yb are taken, decay of material already onsite will be determined.
- The drums that will contain waste radioisotopes will be inventoried and have a unique identifier. Residual activity in waste is included in the overall accounting of Lu and Yb.

4.5 Secure Storage

- Access to the SHINE EU Tx Facility is restricted to authorized personnel and their visitors.
    - Radioactive material shall be stored within a Restricted Area. Restricted Areas are posted as defined in the Radiation Protection Program [1], section 10.2.
    - Unescorted access to the Restricted Area is limited to trained Radiation Workers.

- Other individuals accessing a Restricted Area shall be escorted by a trained radiation worker.

- When not in use, licensed calibration sources shall be stored in a locked cabinet or safe.
  - Access to the secure source storage shall be controlled by the RPU.
- Licensed materials in use shall be under the control of a trained Radiation Worker.

4.6 Transport

- Licensed material shall not be transferred or shipped off site without the approval of the RPU.
- Such transfers/shipments shall be packaged and labeled in accordance with VLG [2], ADR [3], DGR [4] rules and regulations and can only be transferred to a facility licensed or authorized to receive the licensed material.

5 Records

Inventory, receipt, transfer, and disposal records shall be maintained for a minimum of 5 years after the license has been terminated.

6 References

[1] SHINE EU, “NVL2-TECRPT-2023-0017 Rev 0 - SHINE EU Radiation Protection Program”.
[2] Dutch law, “Regeling Vervoer over Land van Gevaarlijke stoffen ”.
[3] “Accord européen relatif au transport des marchandises dangereuses par Route ”.
[4] “IATA Dangerous Goods Regulations (DGR) ”.