SHINE EU Therapeutics production facility leak testing procedure

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Table of Contents

Table of Contents 3
1 Purpose 4
2 Scope 4
3 Responsibilities 4
4 Procedure 5
4.1 General Requirements 5
4.2 Sealed Source Leak Tests 5
5 Records 6
6 References 6

1 Purpose

The purpose of this procedure is to describe leak testing of licensed sources within the SHINE Europe Therapeutics Facility. This procedure implements programmatic requirements described in [1], “SHINE EU Radiation Protection Program”.

2 Scope

The scope of this procedure is limited to leak testing under the RPP at the SHIE EU Tx Facility [1].

3 Responsibilities

Role	Responsibility
Radiation Protection Unit (RPU)	• Ensures that the individual performing leak testing has sufficient training and experience. • Ensures that leak tests are carried out in accordance with established processes. • Works with the radiation workers to decontaminate contaminated areas if necessary. • Works with the radiation workers to develop a leak test plan if necessary. • Reviews and certifies leak test results.
Radiation worker	• Performs leak testing in accordance with established processes. • Documents leak testing results and forwards them to the RPU for review and approval. • Notifies the RPU if leak testing results exceed allowed limits.

4 Procedure

4.1 General Requirements

1. Before allowing an individual to perform leak testing, the RPU shall ensure that the individual has sufficient training and experience to perform leak testing independently.
2. To ensure achieving the required sensitivity of measurements, leak testing samples shall be analyzed in a low-background area.
3. A low-background alpha/beta sample counter shall be used to count samples containing alpha/beta/gamma emitters.

4.2 Sealed Source Leak Tests

- Do not perform leak testing on exempt quantity sources.
- Leak testing of the sealed sources shall be conducted, at a minimum every 12 months for sources with an activity above 1 MBq or containing above 0.02 Re_{inh} in accordance with article 4.11 of [2]. A qualified individual shall perform the following actions:
    - For each sealed source to be tested, complete information on a SHINE Leak Test Certificate, including isotope, activity in MBq, manufacturer, serial number, model, leak test date, ISO-2019 certificate, due date, serial number of instrument(s) used, and instrument calibration date.
    - Use a radiation survey meter to monitor exposure.
    - Prepare a separate wipe sample (e.g., cotton swab or filter paper of minimum 5 cm^2) for each source.
    - Number each wipe to correlate with identifying information for each source.
    - Select instrumentation that is sensitive enough to detect 2 becquerel [55 nanocurie] of radionuclide contained in the sealed source.
    - Determine background for the counting instrument.
    - Wipe the most accessible area where contamination would accumulate if the sealed source was leaking, but do not wipe the surface of a plated or foil source (see manufacturer's instructions).
    - Count each wipe and determine the activity, based on the instrument's background and efficiency.
    - Sign and date the list of sources, data, and calculations. Retain records for a minimum of 5 years.
    - Complete information on a SHINE Leak Test Certificate including alpha activity in Bq, beta/gamma activity in Bq, and forward to the RPU for certification.
    - If the wipe test activity is 185 becquerel [55 nanocurie] or higher, notify the RPU so that the source can be withdrawn from use and disposed of properly. Also, ANVS shall be notified within five days of identifying the leaking source.

5 Records

Leak test records are maintained at least 5 years in accordance with the requirements described in article 4.4 of Vbs [2].

6 References

[1] SHINE EU, “NVL2-TECRPT-2023-0017 Rev 0 - SHINE EU Radiation Protection Program”.
[2] ANVS, “ANVS-verordening basisveiligheidsnormen stralingsbescherming.” [Online]. Available: https://wetten.overheid.nl/BWBR0040581/2023-07-01