NRRC Specific Regulations

Management of Used $^{99}Mo/^{99m}Tc$ Generators

NRRC-R-01-SR16

2025

هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

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Specific Regulation

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Preamble

In accordance with the provisions of the Radiation Safety Regulation (NRRC-R-01 Rev. 0.1), approved by the NRRC's Board of Directors in resolution No. (R/1/1/2022), dated 20 April 2022, chapter (4) section (23). This specific regulation establishes specific criteria for the management of used/depleted $^{99}Mo/^{99m}Tc$ generators.

This specific regulation has been prepared in consistent with International Atomic Energy Agency (IAEA) standards, international best practices, and in accordance with the Kingdom's international commitments, and it has been presented in "the Public Consultation Platform, Istitlaa" for public review, comments, and feedback.

This specific regulation has been approved by the NRRC's CEO Resolution No. 0312653 dated 08/09/2025

Table of Contents

Chapter 1: Objective, Scope, and Definitions..... 9

Section 1: Objective..... 9

Section 2: Scope..... 9

Section 3: Definitions..... 9

Chapter 2: Management Options for Used $^{99}Mo/^{99m}Tc$ Generators..... 11

Section 4: General Requirements..... 11

Section 5: Storage for Decay Until Clearance from the Regulatory Control of Used $^{99}Mo/^{99m}Tc$ Generators..... 11

Section 6: Transfer of Used $^{99}Mo/^{99m}Tc$ Generators to an Authorized Type B Facility Prior to Their Clearance from Regulatory Control..... 13

Section 7: Return of Used $^{99}Mo/^{99m}Tc$ Generators to the Supplier Prior to Their Release from Regulatory Control..... 14

Table of References

Nuclear Material Accountancy and Control (NRRC-R-12 Rev. 0.1)..... 9

Safe Transport of Radioactive Materials (NRRC-R-15 Rev. 0.1)..... 13

Exemption and Clearance Levels (NRRC-R-01-SR01).. 12

Chapter 1: Objective, Scope, and Definitions

Section 1: Objective

1. The objective of this regulation is to set out specific safety requirements for the management of used $^{99}Mo/^{99m}Tc$ generators.

Section 2: Scope

2. This specific regulation applies to facilities that:
   a. Use and manage $^{99}Mo/^{99m}Tc$ generators for medical purposes;
   b. Manage used $^{99}Mo/^{99m}Tc$ generators for non-medical purposes that are not cleared from regulatory control.

3. This specific regulation does not apply to $^{99}Mo/^{99m}Tc$ generators that contain depleted uranium as a shielding. In case depleted uranium is used as a shielding material, refer to the Regulation on Nuclear Material Accountancy and Control regulation (NRRC-R-12 Rev. 0.1).

Section 3: Definitions

Management of used ^{99}Mo - ^{99m}Tc Generator

The possession, storage, transport, handling, or any other activities with the used $^{99}Mo/^{99m}Tc$ generator specified by the NRRC in accordance with the Commission Laws.

Radiation Protection Program

Systematic arrangements that are aimed at providing adequate consideration of radiation protection measures.

Storage

The holding of radioactive sources, radioactive material, spent fuel, or radioactive waste in a facility that provides for their/its containment, with the intention of retrieval.

Supplier (For the purpose of this specific regulation)

Any person or organization that has full or partial responsibilities in relation to the manufacture of $^{99}Mo/^{99m}Tc$ generators or has been recognized by the manufacturer to be fully competent in handling $^{99}Mo/^{99m}Tc$ generators assigned by the authorized person.

Type A Facility

An authorized facility where $^{99}Mo/^{99m}Tc$ generators are used and managed for medical purposes.

Type B Facility

An authorized facility where $^{99}Mo/^{99m}Tc$ generators are used and managed for non-medical purposes.

Used $^{99}Mo/^{99m}Tc$ Generator

Any $^{99}Mo/^{99m}TC$ generator that cannot provide an elution of ^{99m}TC with adequate activity for the performance of any nuclear medicine diagnostic examination.

Chapter 2: Management Options for Used $^{99}Mo/^{99m}Tc$ Generators

Section 4: General Requirements

4. For the management of used $^{99}Mo/^{99m}Tc$ generators in Type A facilities, the authorized person shall select one of the following options:
    a. Store the generators in the facility for decay of radioactivity until their clearance from regulatory control;
    b. Transfer the generators to an authorized Type B facility prior to their clearance from regulatory control; or
    c. Return the generators to the Supplier prior to their clearance from regulatory control.
5. For Type A and B facilities, the authorized person shall ensure that the facility's Radiation Protection Program (RPP) includes provisions to comply with the requirements of this specific regulation.
6. Type B facilities where $^{99}Mo/^{99m}Tc$ generators are used and managed for the purposes of lead recovery, disposal, or any other activities shall have an authorization from the NRRC.

Section 5: Storage for Decay Until Clearance from the Regulatory Control of Used $^{99}Mo/^{99m}Tc$ Generators

7. For the storage of used $^{99}Mo/^{99m}Tc$ generators for Type A facilities in Article 4(a) or for storage at Type B facilities as prescribed in Article 4(b), the authorized person shall ensure that:
    a. The facility's management system includes appropriate procedures for the handling of used $^{99}Mo/^{99m}Tc$ generators;
    b. The handling of used $^{99}Mo/^{99m}Tc$ generators is performed only by trained personnel;
    c. The used $^{99}Mo/^{99m}Tc$ generators are stored in adequately shielded and secured storage areas.

8. When applying for authorization for a Type A or Type B facility, the applicant shall submit to the NRRC the following information:
    a. A description and a diagram of the area where the used generators will be stored;
    b. The type, location, and thickness of the available shielding;
    c. A description of unrestricted areas adjacent to the storage area;
    d. Measures taken to ensure that radiation levels do not exceed the dose constraints approved by NRRC as part of the authorization process;
    e. Procedures for the handling of used $^{99}Mo/^{99m}Tc$ generators;
    f. Applied security measures;
    g. The records are kept on the management of used $^{99}Mo/^{99m}Tc$ generators that ensure traceability until their clearance.
9. Before carrying out any further actions with the used $^{99}Mo/^{99m}Tc$ generators, the authorized person of a Type A or B facility shall ensure that the generators are stored for 60 days from the day they are placed in the storage area and the corresponding clearance levels have been reached as per the specific regulation on the Exemption and Clearance Levels (NRRC-R-01-SR01).
10. After the storage period set in Article 9 is concluded and before carrying out any further actions with the used $^{99}Mo/^{99m}Tc$ generator, the authorized person shall:
    a. Monitor the gamma radiation dose rate and perform beta contamination checks of the components of the used $^{99}Mo/^{99m}Tc$ generator;
    b. Dispose of the column of the used $^{99}Mo/^{99m}Tc$ generator as common waste only if the gamma radiation dose rate at the surface of the column does not exceed the background levels;
    c. Remove any radiation markings from the components of the used $^{99}Mo/^{99m}Tc$ generator that is cleared from the regulatory control.

11. For monitoring gamma radiation dose rates and performing beta contamination checks of used $^{99}Mo/^{99m}Tc$ generators, the authorized person shall ensure that:
    a. Suitable and appropriately calibrated survey meter and contamination monitor are available;
    b. Beta contamination checks are performed using the most sensitive scale of the contamination monitor;
    c. Monitoring of gamma radiation dose rates and beta contamination checks are performed for the whole generator, and separately for the generator's column and shielding;
    d. Records with the results of the monitoring of gamma radiation dose rates and the beta contamination checks are kept.

12. The authorized person shall ensure that the information about the used $^{99}Mo/^{99m}Tc$ generators that have been cleared from regulatory control is:
    a. Recorded;
    b. Retained within the facility's management system; and
    c. Reported to the NRRC upon request.

Section 6: Transfer of Used $^{99}Mo/^{99m}Tc$ Generators to an Authorized Type B Facility Prior to Their Clearance from Regulatory Control

13. The authorized person of a facility transferring a used $^{99}Mo/^{99m}Tc$ generator shall ensure that:
    a. The transfer takes place only to an authorized Type B facility, and
    b. The transfer complies with the relevant requirements of the Regulation on Safe Transport of Radioactive Materials (NRRC-R-15 Rev. 0.1).
14. The authorized person of a facility transferring a used $^{99}Mo/^{99m}Tc$ generator shall record and retain detailed information about the transfer of the generator.

Section 7: Return of Used $^{99}Mo/^{99m}Tc$ Generators to the Supplier Prior to Their Release from Regulatory Control

15. The authorized person of a facility, returning a used $^{99}Mo/^{99m}Tc$ generator, shall ensure that the generator is returned after the decay of radioactivity to the supplier and in accordance with this specific regulation and the related authorization's conditions.

16. The authorized person of a facility returning a used $^{99}Mo/^{99m}Tc$ generator shall record and retain detailed information about the transfer of the generator.

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