

# Supplementary quality control requirements for radionuclide generators

Management licence condition M1748

## Introduction

The Victorian Radiation Act 2005 (the Act) has the objective of protecting the health and safety of persons and the environment from the harmful effects of radiation. The Department of Health and Human Services administers this legislation. The Act seeks to fulfil this objective by establishing a licensing framework to regulate the conduct of radiation practices and the use of radiation sources. Any person who conducts a radiation practice must hold a management licence (unless exempted from that requirement). The management licence holder must comply with every condition of their licence.

Management licence condition M1748 requires compliance with the requirements specified in this document. The purpose of these requirements is to ensure that radionuclide generator produced radioactive material that is intended to be administered to a human meets a minimum quality standard.

## Scope

This document describes the obligations of management licence holders where condition M1748 has been imposed on an authorisation on the management licence. The requirements in this document apply to quality control of radioactive material produced from radionuclide generators.

The requirements are divided into general requirements and specific requirements. The general requirements apply to all radionuclide generators whereas the specific requirements apply to specific types of generators. All management licence holders required to comply with condition M1748 must satisfy the Mandatory requirements. All management licence holders authorised to possess a molybdenum-99/technetium-99m generator must also satisfy Specific requirements part 2.1.

## Mandatory requirements

### 1. General requirements

1.1 The management licence holder must:

- a. ensure that the radionuclide generator is used in accordance with the manufacturer's instructions or a validated protocol that has been approved by the department,
- b. ensure that an expiry date and time is specified<sup>1</sup> in respect of the eluate from each elution on the eluate vial in accordance with manufacturer's instructions or a validated protocol that has been approved by the department,
- c. ensure that quality control tests are performed on the eluate as specified in this document and as recommended by the manufacturer,

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<sup>1</sup> The eluate expiry must be prominently displayed so that it is apparent to any person seeking to use the eluate, and must be included on the label on the eluate vial shield (secondary label).

- d. ensure that the eluate from each elution is visually inspected for cloudiness, particulates and colour,
- e. not knowingly allow eluate that does not meet the quality standard specified in this document or recommended by the manufacturer to be administered to a human,<sup>2</sup>
- f. remove a generator from use if the performance of the generator fails to meet the quality standard specified in this document or recommended by the manufacturer,
- g. not return a generator to service until it is determined through measurements that the performance of the generator meets the quality standard specified in this document and as recommended by the manufacturer,
- h. ensure that any eluate that does not meet a quality standard specified in this document or recommended by the manufacturer is quarantined<sup>3</sup> and clearly labelled with the text “Not for human use”.
- i. ensure that accurate records are retained of the elution and quality control tests specified in this document, including:
  - i. batch number and product details of the generator eluted,
  - ii. unique identification number of each eluate,
  - iii. time and date of each elution,
  - iv. volume of each eluate,
  - v. expiry date and time of each eluate,
  - vi. name of the person who eluted the generator,
  - vii. batch number and product details of saline used in each elution,
  - viii. batch number and product details of the elution vial used in each elution,
  - ix. time and date of each quality control test, and
  - x. name of person who determined whether or not the quality control test results satisfied the quality standard.

## 2. Specific requirements

### Quality Control Standard in respect of molybdenum-99/technetium-99m generators

2.1 A management licence holder who is authorised to possess a molybdenum-99/technetium-99m generator must ensure that the quality control tests specified in Table 1 are performed on the eluate produced from each elution.

**Table 1: Quality control tests and criteria**

Test	Criteria
1. Molybdenum-99 breakthrough	The activity of molybdenum-99 in any 1 MBq of technetium-99m must not exceed 1 kBq at the time of expiry.
2. Aluminium breakthrough	The concentration of aluminium ions must not exceed 5 µg/mL.
3. pH of eluate	The pH must be in the range 4.0 to 8.0

<sup>2</sup> This requirement also applies to radiopharmaceuticals produced from the eluate.

<sup>3</sup> The quarantine must be sufficiently secure so as to prevent a quarantined eluate being administered to humans or used in the production of radiopharmaceuticals for human use. A quarantined eluate must not be reprocessed or combined with another eluate unless this reprocessing or combination is permitted by a validated protocol that has been approved by the Department.

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