South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

8 February 2024

IDENTIFICATION AND LABELLING OF RADIOACTIVE SOURCES AND SOURCE CONTAINERS

The hazardous nature of radioactive sources requires regulatory control and identification to support cradle-to-grave tracking of the sources. Thus, to ensure that the regulatory control of the radioactive sources and source containers, strict regulatory requirements are outlined on this document which requires the radioactive sources and source containers to have clear means of identification from cradle-to-grave.

Document History

Final Version	Reason for Amendment	Effective Date [dd Month yyyy]
1	Old document revision	03 October 2014
2	New document revision	February 2024

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

Contents

Glossary

Abbreviation/ Term	Meaning
SAHPRA	South African Regulatory Products Authority
IAEA	International Atomic Energy Agency

1. INTRODUCTION

Radioactive sources, both sealed and unsealed, are widely used in medical and industrial applications in South Africa. Some of the sources are manufactured in South Africa, while others are imported. The hazardous nature of radioactive sources requires regulatory control and identification to support cradle-to-grave tracking of the sources.

1.1 Purpose

The purpose of these Regulatory Requirements is to ensure that radioactive sources can be traced. This requires clear means of identification of radioactive sources and source containers.

1.2 Scope

These requirements shall apply to all radioactive sources, source containers and equipment containing radioactive sources used in South Africa.

2. LEGAL PROVISION

These Regulatory Requirements are based on:

2.1 International Standards: IAEA Code of Conduct on the Safety and Security of Radioactive Sources: Guidance on the Import and Export of Radioactive Sources.

2.2 The Hazardous Substances Act (15 of 1973) and Regulations R247 of 1993 related to the Act.

2.3 The need for cradle-to-grave tracking of sealed radioactive sources.

3. REGULATORY REQUIREMENTS

3.1 Every sealed radioactive source produced in South Africa, imported into South Africa and/or used in South Africa shall have a uniquely identifiable serial number allocated by the manufacturer's documented numbering system and printed on the source capsule.

3.2 All new radioactive sources produced in South Africa or imported into this country for the first time must be accompanied by a copy of the original calibration certificate. The certificate must always be in the possession of the current owner of the source. The distributor must keep a copy, and a copy must be provided to Radiation Control each time the source changes hands.

3.3 Every item of equipment containing radioactive sources, and every container used to store or transport radioactive sources, must have a container serial number clearly displayed on it.

3.3.1 The container (or equipment) must have a label permanently fixed to it at all times, displaying the following information clearly and legibly:

- the radionuclides(s) (e.g., Cs-137)
- the activity of the source at calibration (e.g., 370 MBq or 1,0 mCi)
- the date of calibration
- the serial number(s) of the source(s) as well as the source container (if applicable)
- the radiation trefoil

3.3.2 The way in which the label is fixed to the container must not degrade the integrity of the radiation shielding.

3.4 A radioactive source may be transferred from one piece of equipment or container to another only by a qualified source handler and in an approved facility, The company responsible for the source transfer must be able to certify the information in 3.3.1 and 3.3.2 above for the new arrangement,

3.5 In the case of sealed radioactive sources, equipment containing radioactive sources, and source containers already in circulation prior to the issuing of these requirements, the authority holder shall provide Radiation Control with clear photos of the equipment/container and of the label as proof of the identity of the source if no calibration certificate is available.

3.6 Special cases that require deviation or exemption from any of these requirements will be considered on an ad hoc basis.

3.7 Any container used for unsealed sources must be labelled with a nonremovable label that includes the information in 3.3.1 as well as the manufacturer's name and the batch number of the radionuclide.

4. EFFECTIVE DATE

These requirements are valid as of the date of approval by SAHPRA.

5. REVIEW OF REGULATORY REQUIREMENTS

These Regulatory Requirements are subject to review as required.

6. PREVIOUS REQUIREMENTS AND CIRCULARS

Any previous Regulatory Requirements and circulars on identification, labelling and certification of radioactive sources are hereby replaced.

7. REFERENCES

The following related documents are referenced:

7.1 International Standards**:** IAEA Code of Conduct on the Safety and Security of Radioactive Sources: Guidance on the Import and Export of Radioactive Sources.

7.2 The Hazardous Substances Act (15 of 1973) and Regulations R247 of 1993 related to the Act.

8. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the RN-REQ-SRC-001. It will be reviewed on this timeframe or as and when required.