

South African Health Products
Regulatory Authority
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GUIDELINE ON IODINE-131 THERAPY

Condition 90 of the Isotope Conditions states that:

Patients who receive a dose > 555 MBq I-131 must be accommodated in an isolation ward. Release of the patient may be authorised when the dose rate at one metre from the patient's neck is $< 25 \,\mu\text{Sv/h}$.

This document describes the requirements for those isolation rooms/ wards and related procedures.

Document History

Final	Reason for Amendment	Effective Date
Version		
1	First issue, industrial comments incorporated and published for implementation	October 2010
2	 Content structured on the new SAHPRA Guideline Template A unique document number SAHPGL-RDN-RN-09 allocated to this Guideline 	December 2022

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SAHPGL-RDN-RN-09_v2 Page 1 of 7

Contents

Docu	ment History	1
Gloss	ary	3
1.	INTRODUCTION	4
1.1	Purpose	4
1.2	Scope	4
2.	LEGAL PROVISION	4
3.	REQUIREMENTS FOR FACILITIES WHERE THERAPEUTIC DOSES OF I-131 ARE ADMINISTERED	4
3.1	Ward	4
3.2	Floor	5
3.3	Waste disposal	5
3.4	Dose calibrator	5
3.5	Radiation monitors	5
3.6	Personal dosimeter (TLD)	5
3.7	Radiation warning sign	5
3.8	Linen	5
3.9	Medical Physicist	6
3.10	Elimination	6
4.	REQUIREMENTS FOR HOSPITALISATION OF CHILDREN FOR I-131 MIBG TREATMENT	6
5.	PRECAUTIONS TO BE TAKEN BY A PARENT WHO WISHES TO BE WITH A CHILD DURING I-131	6
6.	REFERENCES	7
7	VALIDITY	7

Glossary

Abbreviation/ Term	Meaning
I-131	iodine-131
EPD	electronic personal dosimeter
mCi	millicurie, a unit of activity
MBq	megabecquerel, a unit of activity (10 ⁶ becquerel)
mR/h	millirem per hour, a unit a unit of equivalent dose rate (1 rem = 10 ⁻² sievert)
μSv/h	Micro sieverts per hour, a unit of equivalent dose rate (10 ⁻⁶ sieverts per hour)
TLD	thermoluminescence dosimetry/dosimeter

SAHPGL-RDN-RN-09_v2 Page 3 of 7

1. INTRODUCTION

Therapeutic doses of I-131 may be administered as capsules or via drip (in the case of I-131 MIBG). In both cases the resulting radioactivity of the patient, together with the volatility of the I-131, creates a radiation hazard for staff as well as visitors. This guideline seeks to assist radiation oncology facilities to manage that hazard safely.

1.1 Purpose

This guideline seeks to assist staff of radiation oncology facilities to manage the hazards related to I-131 therapy where doses above 555 MBq are administered.

1.2 Scope

The current BSS (IAEA Basic Safety Standards) gives a guidance level of 1 100 MBq for release of Iodine-131 patients (treated by any form of therapy). However, Condition 90 of SAHPRA's Isotope Conditions sets a lower threshold for admission of patients, stating that *Patients who receive a dose* > 555 MBq I-131 must be accommodated in an isolation ward. Release of the patient may be authorised when the dose rate at one metre from the patient's neck is < 25 μ Sv/h.

2. LEGAL PROVISION

The use of I-131 is subject to the provisions of:

- the Hazardous Substances Act 15 of 1973, as amended (HSA),
- the Regulations relating to Group IV Hazardous Substances, made in terms of section 29 of the Hazardous Substances Act 15 of 1973 and published under Government Notice R247 in Government Gazette 14596, dated 26 February 1993 (R247), and
- SAHPGL-RDN-RN-06_v1 Guideline for the Safe Use of Unsealed Radioactive Sources.

3. REQUIREMENTS FOR FACILITIES WHERE THERAPEUTIC DOSES OF I-131 ARE ADMINISTERED AND PATIENTS ARE HOSPITALISED

3.1 Ward

Patients who are admitted must be accommodated in a special designated ward with an en suite toilet and shower for their exclusive use. If the shower is over a bath, it must have a wall attachment (so that the patient does not have to hold it while showering). The patient must be instructed not to bath but only to shower, to ensure that the I-131 is properly rinsed off the skin. The bath plug should be removed to reduce the temptation to soak in the bath.

SAHPGL-RDN-RN-09_v2 Page 4 of 7

3.2 Floor

The floor of the ward must be of non-absorbent material such as linoleum or vinyl with sealed joints. Failing this, the floor must be covered with sheets of plastic or absorbent paper.

3.3 Waste disposal

A receptacle, lined with a plastic bag, must be placed at the door inside the ward for discarding contaminated articles such as gloves, aprons and overshoes.

3.4 Dose calibrator

An isotope calibrator must be available to verify the activity administered to a patient. The instrument must be checked with a sealed source before measuring the activity.

3.5 Radiation monitors

An exposure meter must be available for monitoring the dose rate from the patient to quantify the time and distance that staff and family may attend the hospitalised patient. A monitor must be available for routine contamination monitoring of working surfaces, and for use in the event of any accidental spillage. The personnel must use this monitor to monitor their hands, clothes and shoes prior to leaving the ward.

3.6 Personal dosimeter (TLD)

Nursing personnel who do not wear personal dosimeters must be issued with direct-reading pocket dosimeters (EPDs). The daily readings must be noted in a logbook, which must be available for inspection purposes.

Any person who is likely to receive more than 3/10 of the annual dose limit for radiation workers must wear a personal dosimeter (TLD).

3.7 Radiation warning sign

A removable radiation warning sign, which displays the name of the patient, the nuclide, activity, time and date administered must appear on the door of the ward.

Comprehensive instructions for nursing staff regarding appropriate specialised patient care and monitoring requirements must be displayed at the radiation warning sign on the door.

3.8 Linen

The mattress must be covered with non-absorbent material.

No articles and/or linen may be removed from the ward without prior monitoring for contamination.

SAHPGL-RDN-RN-09_v2 Page 5 of 7

Following the discharge of the patient, the ward and linen must be thoroughly monitored for contamination. Contaminated linen must be washed separately.

3.9 Medical Physicist

A medical physicist must be available to perform the following duties, among others:

- 3.9.1 Supervise the administration of therapeutic doses: a physicist must be present at administration of all doses above 555 MBq (15 mCi).
- 3.9.2 Supervise monitoring of personnel, patients and family members (parents).
- 3.9.3 Monitor the patient to determine that the dose rate at one metre from the thyroid is below 25 μ Sv/h (2,5 mR/h) before the patient is discharged.

3.10 Elimination

The faeces and urine of patients receiving therapeutic doses of radionuclides can be disposed of into the sewage system as non-radioactive waste. They need not be stored for any time, and the activity therein need not be included when calculating total radioactivity releases from the hospital.

4. REQUIREMENTS FOR HOSPITALISATION OF CHILDREN FOR I-131 MIBG TREATMENT

- 4.1 See the requirements 3.1 3.10 above.
- 4.2 Used nappies must be placed in plastic bags, which must be sealed, labelled and stored in the radioactive waste store.
- 4.3 The child may only be discharged when the estimated activity of iodine present in the body of the patient has reduced to below 15 mCi.
- 4.4 Adults are allowed to be present while children receive MIBG treatment, but not to nurse or change nappies (see section 5 below).

5. PRECAUTIONS TO BE TAKEN BY A PARENT WHO WISHES TO BE WITH A CHILD DURING I-131 TREATMENT

5.1 The parent must be issued with a direct-reading dosimeter (EPD) for the period of treatment. The radiation dose equivalent should be kept below 1.2 mSv (120 mrem) per treatment, assuming repeated treatments take place at intervals greater than four weeks.

SAHPGL-RDN-RN-09 v2 Page 6 of 7

- 5.2 The parent must be given thyroid-blocking treatment (with stable iodine) before and during the patient's stay in hospital.
- 5.3 Direct nursing of the patient by the parent must be limited. For example, the parent should not be allowed to change nappies.
- 5.4 Pregnant women are not permitted to be with children during treatment.

6. REFERENCES

The following related documents are referenced:

- 6.1 The Hazardous Substances Act 15 of 1973, as amended (HSA).
- 6.2 Regulations relating to Group IV Hazardous Substances, made in terms of section 29 of the Hazardous Substances Act 15 of 1973 and published under Government Notice R247 in Government Gazette 14596, dated 26 February 1993 (R247).
- 6.3 SAHPGL-RDN-RN-06 Guideline for the Safe Use of Unsealed Radioactive Sources, SAHPRA Radiation Control.

7. VALIDITY

This guideline is valid for a period of five years from the effective date of revision and replaces the old guideline for lodine-131 Therapy, revised in October 2010. It will be reviewed on this timeframe or as and when required.

SAHPGL-RDN-RN-09_v2 Page 7 of 7