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

12 December 2022

GUIDELINE FOR REPORTING NATIONAL RADIATION OCCURRENCES

The purpose of this guide is to provide clarity on the reporting of various types of radiation incidents, accidents and other unusual radiation events that must be reported to SAHPRA Radiation Control through the office of the Radionuclides subunit.

It is the responsibility of all employees to ensure that any unusual or unexpected radiation event or exposure affecting themselves or others is reported immediately to the Authority Holder and the RPO/ARPO, who then have a legal responsibility to notify Radiation Control as appropriate.

Document History

Final Version	Reason for Amendment	Effective Date
1	First issue, industrial comments incorporated and published for implementation	March 2018
2	- Content structured on the new SAHPRA Guideline Template - Old guideline no. GLN-RN900 INCIDENT changed to unique document number SAHPGL-RDN-RN-12 - Form RN900 changed to **GLF-RDN-RN-12A**	December 2022

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

Contents

Glossary

Abbreviations and definitions	
AMP	Acting medical physicist (applicable to radiation oncology and nuclear medicine facilities only)
ARPO	Acting radiation protection officer
CATS	Crimes against the State – a unit within the South African Police Service (SAPS)
IAEA	International Atomic Energy Agency
INES	International Nuclear Event Scale
ITDB	Illicit Trafficking Database
MP	Medical physicist (applicable to radiation oncology and nuclear medicine facilities)
R247	Regulations relating to Group IV Hazardous Substances, made in terms of section 29 of the Hazardous Substances Act 15 of 1973 (HSA) and published under Government Notice R247 in *Government Gazette* 14596, dated 26 February 1993.
RPA/RPS	Radiation protection adviser / Radiation protection specialist.
RPO	Radiation protection officer

Terms and definitions	
Contamination	(1) The presence of any radioactive substance on surfaces or within solids, liquids or gases (including the human body) where it is unintended or undesirable, or (2) any process giving rise to its presence in such places.
Contamination incidents	○ **Minor contamination incident:** An abnormal occurrence involving low amounts of radioactive materials, where the worker handling the spill knows how to clean it up, has the decontamination materials on hand, and can respond within a reasonably short time without incurring a risk of exposure or spreading.
	○ **Major contamination incident:** An abnormal occurrence involving large amounts of radioactive material, high-risk radionuclides, large contaminated areas, contamination of the skin, airborne radioactivity, or any situation where the contamination may have spread outside the authorised area.
Defence in depth	The application of multiple independent protective measures for a given safety objective, so that the objective is achieved even if one of the protective measures fails.
Emergency	A non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes radiation emergencies as well as conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes. It also includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.

Emergency exposure situation	A situation of exposure that arises as a result of an accident, a malicious act, error or any other unexpected event, and requires prompt action in order to avoid or reduce adverse consequences.
Medical physicist	A health professional with specialist education and training in the concepts and techniques of applying physics in medicine, who is competent to practise independently in one or more of the subfields (specialties) of medical physics and is registered with the HPCSA as a medical physicist.
Near miss	An unplanned event that could have caused unplanned radiation exposure or a release or spill of radioactive material, but which did not, in fact, result in such exposure. Only a fortunate break in the chain of events prevented injury, fatality or damage. In other words, a miss that was nonetheless very near. A near miss could be due to human error, faulty processes, system faults or a consequence of a sequence of actual events.
Radiation generator	A device capable of generating ionising radiation such as X-rays, neutrons, electrons or other charged particles, and which may be used for scientific, industrial or medical purposes.
Radiation incidents and accidents	○ **Radiation incident:** Any unintended or ill-advised event, when using ionising radiation apparatus or radioactive substances, which results in, or has the potential to result in, the exposure of any person or the environment to radiation beyond the levels normally expected for a particular practice. This includes events that result from operator error, equipment failure, or the failure of management systems and that warrant investigation. In the context of reporting and analysis of events, the word incidents is used to describe events that are less severe than accidents.
	○ **Radiation accident:** Any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety. A radiation incident that has led to significant consequences for people, the environment or the facility.
Radioactive material	Material designated in national law or by a regulatory body as being subject to regulatory control because of its radioactivity.
Radioactive sources	○ **Sealed radioactive source:** Radioactive material that is permanently sealed in a capsule or closely bonded and in a solid form.
	○ **Unsealed radioactive source:** Radioactive material that is not permanently encapsulated, but usually contained in a vial or generator, e.g. Mo-99/Tc-99m generator. Unsealed sources can be in solid, liquid or gas form. (Note that brachytherapy seeds are usually treated as unsealed sources.)
	○ **Disused radioactive source:** A radioactive source that is no longer used, and is not intended to be used, for the practice for which an authorisation has been granted. Note that a disused source may still present a radiological hazard.
	○ **Orphan source**: A radioactive source that is not under regulatory control, either because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen, or otherwise transferred without proper authorisation.

Radioactive sources (continued)	○ **Spent radioactive source:** A radioactive source that is no longer suitable for its intended purpose because of radioactive decay. (Also called a depleted source.) Note that a spent source may still present a significant radiological hazard. Also note that, in practice, many spent sources may no longer be usable because their encapsulation has passed its recommended working life, or the equipment containing them is no longer in use.
	○ **Vulnerable radioactive source:** A radioactive source that is not under adequate control to ensure long-term safety and security, making it relatively easily for unauthorised persons to acquire or relatively liable to become orphaned.
Radiation Safety	The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, to ensure protection of workers, patients, the public and the environment from undue radiation hazards.
Radiation Security	The prevention or detection of, and response to, theft, sabotage, unauthorised access, illegal transfer or other malicious acts involving radioactive substances or their associated facilities.
Safety and security culture:	A *safety culture* is a set of characteristics and attitudes that drives organisations and individuals to make protection and safety issues their top priority.
	A *security culture* is characterised by beliefs, attitudes, behaviour and management systems that lead to more effective security.
	Safety and security share the common aim of protecting human life and health and the environment. In both design and implementation, safety and security measures should be integrated so that they do not interfere with or compromise one another. A dynamic and effective safety and security culture should exist at all levels of the Authority Holder's staff and management.

1. INTRODUCTION

Radiation incidents, accidents and other unusual radiation events occur from time to time. According to the Regulations (R247, February 1993) relating to Group IV Hazardous Substances, an Authority Holder who becomes aware of such an occurrence must notify the Regulator (now SAHPRA Radiation Control) "forthwith", and the initial notification must be followed up by a written report within seven days (see 4.2 below for details).

1.1 Purpose

The purpose of this guide is to provide clarity on the reporting of various types of incidents that must be reported to SAHPRA Radiation Control through the office of the Radionuclides Subunit.

1.2 Scope

The Authority Holder and the RPO/ ARPO have a legal responsibility to protect the health, safety and welfare of their employees, radiation workers, the public, patients (where applicable) and the environment through the management of radiation protection, radiation safety and security of all radioactive sources in their authority.

It is the responsibility of all employees to ensure that any unusual or unexpected radiation event or exposure affecting themselves or others is reported immediately to the Authority Holder and the RPO/ ARPO, who then have a legal responsibility to notify Radiation Control as appropriate.

2. LEGAL PROVISION

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) require an Authority Holder who becomes aware of a radiation occurrence to notify the Regulator (now SAHPRA Radiation Control) "forthwith", and the initial notification must be followed up by a written report within seven days.

3. WHICH INCIDENTS OR ACCIDENTS TO REPORT

The following types of incidents/ accidents must be reported to the Radionuclides Subunit of SAHPRA Radiation Control:

3.1 Lessons learned

(a) Any **near miss** (no actual exposure – see earlier definition)
(b) Any unplanned event that **caused unnecessary exposure** to a radiation worker, member of the public or patient, but caused **no significant clinical harm** to the person(s) concerned

(c) Any unplanned alarming / concerning / notable event that should be **communicated to other users as a lesson learned**.

3.2 Incidents that cause or may lead to radiation injuries or radiation doses exceeding the annual dose limits1 to workers or members of the public

(a) Note that situations where radiation injuries or high doses occur must be reported to the Radiation Control as soon as possible, and certainly within 24 hours.[2] "High doses" here are those exceeding 0.25 Sv whole body dose, 0.75 Gy organ dose, or 6 Gy skin dose.

(b) Any inadvertent exposure greater than 1 mSv to a human embryo or foetus must be specifically noted in the report. (This applies to radiation workers as well as members of the public.)

3.3 Medical exposure of patients involving use of radioactive sources

(a) Any inadvertent exposure to the embryo or foetus while performing a radiological procedure

(b) Administration of the wrong radionuclide, or to the wrong patient or the wrong tissue, or by the wrong route

In nuclear medicine:

(c) Any incident where the activity of the radionuclide administered differs from the activity prescribed in the hospital/practice standard protocol for that test, and the difference is clinically significant

(d) Any diagnostic procedure other than as prescribed by the medical practitioner

(e) Any diagnostic procedure resulting in an observable acute radiation effect

(f) The omission of an intended thyroid block before I-131 MIBG administration

In radiotherapy:

(g) Any incident where the activity of a radionuclide administered differs from the prescribed activity, and the difference between the actual and intended activities is clinically significant

(h) During administration of a therapeutic dose of radiation from an apparatus containing a radioactive source, any incident where the deviation of the delivered dose from the total prescribed treatment dose is clinically significant.

Collection of information on incidents in the medical sphere: The fundamental role of an incident reporting system is to enhance patient safety by learning from mistakes. The Authority Holder is encouraged to maintain regular monitoring and checking, with a good governance and risk management

[1] See section 5 of this document.

[2] ARPANSA 2011, *National Directory for Radiation Protection*, Radiation Protection Series No. 6, July 2011, p37.

system, clinical audits and quality assurance programmes. A recording system for these non-notifiable radiation incidents is advisable, even though they are not reportable to Radiation Control.

3.4 Loss or theft of radioactive sources or radiation apparatus containing radioactive sources

Note section 4.2 (a) regarding reporting to SAPS CATS.

3.5 Incidents related to transport of radioactive material

(a) Where a package is lost or misrouted during transport

(b) Where a package is damaged during freight handling or transport

(c) Where a package is transported without the required documentation or correct labelling

(d) Where the package is contaminated or the radiation levels on the outside of the package exceed those stated on the label

(e) Where a transport package used (usually by a manufacturer or distributor of radioactive sources) does not comply with international standards.

3.6 Damage to, or malfunctioning of an apparatus containing or used with radionuclides

Where the damage or malfunction could in any way affect the radiation safety of the apparatus, including issues such as shielding integrity or causing increased radiation levels.

3.7 Contamination with, or dispersal of, a radioactive material

(a) Any fixed skin contamination greater than 3 Bq/cm^2 for α-emitters and 30 Bq/cm^2 for β- and γ-emitters remaining after 24 hours.[3]

(b) Where a surface, substance or material is contaminated by a radioactive substance resulting from the spillage of more than 100 times the exempt activity of that substance specified in IAEA GS-R Part 3[4] Table I-1.

3.8 Unintentional or unauthorized discharges of radioactive materials into the atmosphere or environment

When the unintentional or unauthorised activity discharged exceeds 100 times the exempt activity for that radionuclide specified in IAEA GSR Part 3 Table I-1.

[3] JSP392 Leaflet 14, s 18.4

[4] https://www.iaea.org/publications/8930/radiation-protection-and-safety-of-radiation-sources-international-basic-safety-standards

3.9 Unintended intake

Unintended intake of radioactive material by ingestion, inhalation or a via contaminated wound.

3.10 Radiation source out of control

Situations where a radiation source is out of control. “Out of control” means, for example, that the source is not safely secured or shielded, or contamination is not confined. It includes:

(a) radioactive sources being in any unintended location or in scrap metal

(b) sources being left unattended

(c) unauthorised possession of radioactive sources

(d) the discovery of orphan radioactive sources.

3.11 Emergencies / emergency exposure situations

Any emergency exposure or other emergency situation. For example, when there is a fire in a facility where radioactive sources were used or stored, no material may be removed in clearing-up operations until the sealed sources have been removed and/or the area has been surveyed for contamination.

Note that in an emergency exposure situation, the preservation of life takes precedence, though one must try to limit contamination and exposure as far as realistically possible.

3.12 Notification by medical practitioners and other persons

Where a medical practitioner is of the opinion that a person has been exposed to ionising radiation to such an extent that medical treatment is required or that the person needs to be removed from his or her particular working conditions, the medical practitioner shall notify SAHPRA Radiation Control of the situation.[5]

3.13 Other incidents that, in the opinion of the Authority Holder, warrant reporting

Some examples:

(a) Potentially hazardous situations that could serve as a warning to other users

(b) Triggering of radiation monitors at entrances to scrap-metal processing plants or landfill sites.

4. REPORTING INCIDENTS/ACCIDENTS

4.1 Who should report incidents/accidents to SAHPRA Radiation Control?

(a) The Authority Holder, RPO or ARPO, MP or AMP, or RPA.

[5] R247 (February 1993) Regulation 19

(b) Any staff member who becomes aware of an incident/ accident and suspects that it was not reported to or by the manager/ RPO

(c) Any patient or member of the public

(d) Any person who becomes aware of an incident/ accident or a radioactive source out of control that may lead to potential radiation exposure to any person or the environment

(e) Occupational health and safety officers

(f) Managers of scrap-metal processing plants.

A feature of a high safety and security culture is that every individual takes responsibility to report any radiation incident/accident, regardless of whether it took place at his/her own facility or at any other facility or location. The principle is that we all collectively contribute to the enhancement of safety and security in our environment.

Note: Scrap-metal processors should not reject a consignment that contains a radioactive source, but rather accept it and call for assistance to remove the source from the consignment. This is to prevent radioactive sources being discarded elsewhere, where there may be a greater danger of exposing the public.

4.2 Reporting procedures

4.2.1 Initial notification of radiation occurrence

SAHPRA Radiation Control must be notified immediately of the radiation occurrence. The initial notification may be done by telephone or e-mail; however, this must be followed as soon as reasonably possible – and certainly within 7 days – by a completed notification form **GLF-RDN-RN-12A** *(Old Form RN900[6])*. Staff of the Regulator may offer technical advice or access support services where needed.

In the event of theft, the case must also be reported at the nearest police station to obtain a case number, which must be recorded on the Incident notification form **GLF-RDN-RN-12A** *(Old Form RN900)*. The local police must be alerted specifically that the case must be referred to the CATS (Crimes against the State) unit for further investigation.

4.2.2 Compiling an incident/accident report

The initial radiation occurrence notification must be followed within seven days[7] by an incident/accident report giving a detailed description of the event, preferably on form **GLF-RDN-XR-12A** *(Old Form RN900)*. Where a company or hospital is already using reporting form that is at least as a clear and detailed as

6 Incident notification form, available from www.sahpra.org.za (HEALTH PRODUCTS tab).

7 R247 (February 1993) Regulation 16

the **GLF-RDN-RN-12A** *(Old Form RN900)*, that may be acceptable, at the discretion of Radiation Control. The report must contain, as a minimum, the following headings and information, as applicable to the occurrence:

- Introduction
- Date and time of the radiation occurrence
- Site and/or situation description (including source information, number of persons involved, their work routine and duties performed at the time, and their contact details, doses, etc)
- Event description (sequence of events including adherence to working procedures, communication to stakeholders, etc.)
- Estimation of severity of the event
- Immediate consequences and urgent corrective measures taken to lessen consequences
- Long-term consequences
- Number of persons affected, including a description of the effects as well as methods to determine the effective dose(s), treatment and/or corrective measures taken
- Quantities of radionuclides involved
- Results of radiation monitoring or surveys or records (including make, model and date of calibration of instruments, as appropriate)
- Readings on personal dosimeters (TLDs) or electronic pocket dosimeters (EPDs)
- Root cause analysis
- Summary of local orders, work procedures, safety documents, equipment manuals, maintenance programmes
- Discussion
- Suggested remedial action, including communication to stakeholders, if applicable
- Conclusion.

4.2.3 Estimation of the severity of the accidental exposure

The severity of the accidental exposure is determined by:

- the type of radiation (α, β, γ radiation, neutrons; sealed or unsealed sources; external and/or internal exposure)
- the number of persons involved
- the time spent close to the source
- the distance from the source
- the direction of the beam (if it was a collimated source)

- the shielding.

4.3 Confidentiality

(a) A person who carries out or assists with an investigation related to patients shall keep confidentiality in respect of all facts which come to his or her notice in the performance of his or her functions and shall not disclose any such information to any person except the Authority Holder, RPO and staff of the Regulator. Information contained in reports shall be kept confidential.

(b) No personal particulars regarding a patient shall be disclosed to any person except by order of a court.

5. DOSE LIMITS

	Occupational dose limits	**Public dose limits**
Effective dose	20 mSv per year, averaged over five years, and not more than 50 mSv in any one year	* 1 mSv per year
Annual equivalent dose to the:		
eye (lens)[8]	20 mSv	1 mSv
skin	500 mSv	50 mSv
hands and feet	500 mSv	-

* In exceptional cases, this limit may be exceeded, provided that the average over five years remains less than 1 mSv per year.

Note: Limits for pregnant radiation workers

Additional restrictions to the above occupational dose limits apply in the case of pregnant women. When pregnancy has been diagnosed, the embryo/foetus must be protected by applying a supplementary equivalent dose limit of 2 mSv *to the surface of the woman's abdomen* (lower trunk) for the remainder of the pregnancy.

The embryo/foetus is recognised as a member of the public and is therefore subject to the dose limit of 1 mSv. However, where the mother is a radiation worker, the standard practice is to use a

[8] The dose limits for the lens of the eye are in line with the recommendations in ICRU Publication 103. These limits are lower than in Annexure 2 to R247.

limit of 2 mSv on the surface of her abdomen, rather than 1 mSv to the foetus, since it is easy to measure the dose to the woman's abdomen with an EPD.

When a female radiation worker informs the Authority Holder that she is pregnant, she shall be removed from any duties that put the embryo/foetus at risk of being exposed to radiation doses that could exceed the annual dose limit. Refer to Regulations R247 of 1993, Section 14 (3)(a).

6. REFERENCES

The following related documents are referenced:

6.1 ARPANSA (Australian Radiation Protection and Nuclear Safety Agency). 2011. *National Directory for Radiation Protection*. Radiation Protection Series No. 6.

6.2 IAEA (International Atomic Energy Agency). 2011. IAEA Safety Standards. *General Safety Requirements Part 3*. No. GSR Part 3 (Interim).

6.3 JSP392 – see United Kingdom Ministry of Defence. 2011.

6.4 R247 – see South Africa. 1993.

6.5 South Africa. 1973. Hazardous Substances Act, No.15 of 1973. Pretoria: Government Printer.

6.6 South Africa. 1993. Regulations relating to Group IV Hazardous Substances. Published under Government Notice R247 in *Government Gazette* 14596 of 26 February 1993: Regulations 16, 19, 24, 25, 29.

6.7 United Kingdom Ministry of Defence. 2011. *JSP 392: Radiation Safety Handbook Volume 2*. Leaflet 14: Investigation, notification and reporting of unusual radiation events (revised Mar09) . Available online from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/27797/Leaflet14ReportingMar09.pdf

7. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old Guideline for Reporting Radiation Occurrences (GLN-RN900 INCIDENT), revised March 2018. It will be reviewed on this timeframe or as and when required.