

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

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# GUIDELINE ON THE ORGANISATIONAL REQUIREMENTS FOR AUTHORITY HOLDERS AND THEIR APPOINTED RADIATION PROTECTION OFFICERS

This guideline sets out the responsibilities of authority holders and their radiation protection officers with respect to activities involving the use of radioactive sources (Group IV hazardous substances), as explained in the Hazardous Substances Act 15 of 1973.

## **Document History**

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## Glossary

Abbreviation/ Term	Meaning
ARPO	Acting radiation protection officer
HPCSA	Health Professions Council of South Africa
NECSA	The South African Nuclear Energy Corporation
NMISA	National Metrology Institute of South Africa
R247	R247: 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.
RPO	radiation protection officer
SABS	South African Bureau of Standards

### **1. INTRODUCTION**

Good radiation safety practice and the achievement of satisfactory working conditions depend on the effective organisation of health physics and safety. The holder of the authority for the use of radioactive material is responsible for the radiological safety of the workers in his operation and that of members of the public liable to exposure as a result of the radioactive material.

#### 1.1 Purpose

The purpose of this guideline is to assist the authority holders to comply with regulatory requirements that deal with the organisational requirements, and their appointed radiation protection officers (RPO) in respect of group IV hazardous substances.

#### 1.2 Scope

The guideline provides regulatory requirements in relation to roles and responsibilities of the RPO which include the organisational responsibility pertaining to medical surveillance, radiation signs, monitoring and calibration, monitoring of controlled areas, limitation of exposure to radiation, registration of sealed sources, to ensure compliance to the legislature governing the safety use of radioactive materials.

#### 2. LEGAL PROVISION

This guideline is based on R247<sup>1</sup>, an in particular Regulations 6 to 11. See also Regulations 25 and 26.

#### 3. RADIATION PROTECTION OFFICER

A person with the necessary knowledge and experience must be appointed to accept, on behalf of the holder of the authority, the responsibility for the safe use of all radioactive material under the holder's control and to observe any statutory requirements in connection with the use of radioactive material. An alternate for the RPO, to whom the duties of the RPO may be delegated, must also be nominated. However, the authority holder remains responsible for the entire extent of radiation protection with regard to any Group IV hazardous substance in respect of which they hold an authority. (See Regulation 5 of R247.)

The RPO's knowledge and experience in the field of radiation protection must be adequate, considering the potential radiation hazards attached to the use of the radioactive material under his/her control. For example, complex procedures involving unsealed sources of relatively high activity will require more knowledge and

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.

experience than handling of equipment containing sealed sources that form an integral part of the equipment.

**NOTE:** It is recommended that the RPO attend appropriate courses in radiation protection. Whenever necessary, the RPO should call for advice or assistance from professionally competent persons.

## 4. DUTIES OF THE RADIATION PROTECTION OFFICER

The RPO must ensure the following:

- (a) New personnel are instructed in safe working practices and in the nature of the biological effect resulting from overexposure to radiation.
- (b) Operational procedures are so established and maintained that the radiation exposure of each worker is kept as far below the authorised limits as is practicable.
- (c) Each case of excessive or abnormal exposure is investigated to determine its cause, and steps are taken to prevent reoccurrence.
- (d) Monitoring devices for personnel are used where required and the records are kept of the results of such monitoring.
- (e) Adequate records are kept of all sources, indicating the locations of these sources or the name of the person to whom they have been assigned.
- (f) Periodic radiation surveys are conducted where required and, if needed, records of such surveys are kept, including descriptions of corrective measures.
- (g) All shields, containers and handling equipment are maintained in a satisfactory condition.
- (h) Periodic leak tests are performed on sealed sources.

## 5. CLASSIFICATION OF WORKERS

Where persons are employed at institutions where radioactive material is used or at installations, it is necessary to distinguish those persons who as a result of their duties are potentially liable to exposures in excess of three tenths of the whole body annual effective dose limit for radiation workers. All such persons must be classified as radiation workers, other workers must not be classified as such.

It is advisable to limit the number of radiation workers as far as practicable. Measures must be taken to ensure that the exposure of non-radiation workers to radiation sources is kept to a minimum, but in any event the exposure may not exceed the authorised limits. This can be achieved by limiting work with radioactive material to controlled areas to which only radiation workers have access.

## 6. **REGISTER**

The holder must compile, in respect of all radiation workers, a register that contains at least the following information for each radiation worker:

- (a) results of pre-employment and routine medical examinations,
- (b) a record of effective doses and exposures recorded by personal pocket dosimeters, respectively, and
- (c) any other relevant information.

## 7. MEDICAL SURVEILLANCE

Radiation workers must be medically examined before employment as radiation workers, and then in accordance with regulation 15 of Government Gazette No. R247 promulgated on 26 February 1993. Medical examinations may also be necessary in the event of over-exposure or of radiation incidents where the possibility of over-exposure exists.

Only persons declared by a medical practitioner (e.g., registered with HPCSA) as being medically fit for radiation work may be employed as radiation workers.

## 8. **REGISTER OF SEALED SOURCES**

The holder must keep, in respect of all sealed sources register that contains at least the following information:

- (a) the nuclide, activity, and date on which the activity was specified,
- (b) the date received,
- (c) the purpose for which the source is used,
- (d) particulars of leak test, and
- (e) particulars of disposal or discarding of the source.

## 9. RADIATION WARNING SIGNS

Radiation warning signs must be displayed at all entrances, storage places, in areas where radioactive sources are used or installed, and where persons could be exposed to ionising radiation.

A list of the names and telephone numbers of persons who can be called in case of an emergency must be prominently displayed in the locations referred to above.

## **10. MONITORING AND CALIBRATION**

#### **10.1** Monitoring of persons

#### 10.1.1 General

The monitoring of persons means routine measurements of the dose equivalents or persons exposed in the course of their work to radiation from external sources and, where applicable, from internally deposited radioactive material. Measurements of the latter will be required only where unsealed sources are used, or where leakage of a sealed source has occurred, and where the possibility of ingestion of radioactive material exists. Unless specifically exempted by the regulatory authority, all radiation workers must be monitored to determine their dose equivalents due to radiation from external sources (see 10.1.2), but guidance regarding the need for internal monitoring must be sought from the regulatory authority.

#### 10.1.2 Monitoring for external sources of radiation

All radiation workers must be issued with personal dosimeters, in addition, when working under areas such that the radiation workers are liable to an exposure from gamma radiation in excess of 200  $\mu$ Sv (20 mR) during any one day, direct-reading dosimeters such as pocket dosimeters must also be issued to the radiation workers.

**NOTE:** The purpose of the pocket dosimeter is for the worker to establish at intervals during the day the rate at which he/she is exposed to radiation and to enable him/her, if necessary, to change working procedures or working conditions to reduce radiation exposures. Pocket-dosimeters reading must be recorded at the end of each working day and these recordings must be filled in the register at the end of each week. This record can be an important source of information when incidents indicated by or over-exposures recorded on personal dosimeters are investigated at a later stage.

#### 10.1.3 Monitoring for internally deposited radioactive material

Where unsealed sources are used, it may be necessary, in addition to taking personal dosimeter reading, also to monitor for any ingestion of radioactive material. This may be done by whole body counting or by analysis of body excretions, or both. The techniques involved are of a complicated and specialised nature and it is advisable to consult the regulatory authority in this regard. Whole body counters are available at most of the training hospitals located in the main centres.

#### 10.2 Monitoring of controlled areas

#### 10.2.1 General

A systematic program of monitoring of controlled areas must be established to ensure satisfactory working

conditions and working procedures and thereby limit the exposure of persons to radiation. The three types of monitoring involved are:

- (a) The monitoring of radiation from radioactive sources (See 10.2.2);
- (b) The monitoring for surface contamination (See 10.2.3);
- (c) The monitoring for air contamination (See 10.2.4).

#### 10.2.2 Monitoring of direct and scattered radiation from radioactive sources

All areas around radioactive sources where persons could be exposed to direct or scattered radiation (or both) must be monitored. Adjoining areas or rooms and, where applicable, areas outside building must be included as these could also be occupied. Monitoring must be conducted before the start of a project, during its progress and after significant modifications to existing installations have been made.

Portable ionisation chambers, Geiger-Muller counters and scintillation counters may be used, as applicable. In some cases, thermoluminescent dosimeters, film dosimeters or digital dosimeters mounted at strategic places, could be used.

#### **10.2.3** Monitoring for surface contamination (unsealed)

Every object used for work with unsealed radioactive material is subject to contamination. This includes work surfaces, walls, floors, clothing and equipment. Contamination by radioactive substances on work surfaces, clothing and equipment may be a significant hazard to health and may also interfere with the work being carried out.

All areas where radioactive material has been used and all equipment that has been in contact with radioactive material must be monitored systematically for contamination. Such monitoring must be performed at least when the work has been completed and, if necessary, also at appropriate times during work periods. Whenever they leave the work area, persons (and their clothing) must be monitored so that the spread of contamination is prevented and contained.

The permitted levels of surface contamination as laid down by the Regulator are given in Table 1.

Monitoring may be performed with the aid of contamination monitoring instruments and by the taking of smear samples. The instruments used must be suitable for the type of radiation emitted by the radionuclides used, e.g., alpha emitters and soft beta emitters will make the use of alpha scintillation monitors and thin end-window Geiger-Muller counters essential (see 10.2.5).

#### Table 1: Permitted levels of surface contamination

	" Inactive area", parts of the body, clothes etc,	Active areas, protective clothing, glassware etc.
Alpha emitters:	0.3 Bq/cm <sup>2</sup>	3 Bq/cm <sup>2</sup>
Beta/gamma emitters:	3 Bq/cm <sup>2</sup>	30 Bq/cm <sup>2</sup>

The measurement may be averaged over 100 cm<sup>2</sup>.

#### **10.2.4** Monitoring for air contamination

In situation where radioactive gases, aerosols, powders or dust are handled or produced, the air must be monitored for contamination.

Where it is possible that, notwithstanding filtration of air exhausted to the atmosphere, the activity released might exceed levels set by the regulatory authority, a reliable system of air monitoring must be employed.

NOTE: When aerosols are to be monitored, the airborne substances are caused to be deposited by electrostatic precipitation, impactors or filtration.

Some radioactive gases can be monitored only after collection by chemical or other means.

#### 10.2.5 Suitability of monitoring equipment

Monitoring equipment must be carefully selected to ensure it has an adequate response to the type of radiation to be measured, and that the equipment exhibits a minimum energy dependence over the range of energies concerned. For example, a monitor designed to measure high-energy from, for example, cobalt-60 or iridium-192 sources may well have a very poor response to lower energy radiation emitted by sources such as americium-241, and iodine-125 and will probably not be acceptable of detecting beta radiation at all. (Detection of the latter would require a thin end – window Geiger-Muller counter or a scintillation monitor).

#### **10.2.6 Recording of results**

Records must be kept of the results of environmental monitoring and of significant events concerning radiation protection. In investigations, such records will usually be the only available source of data.

## **11. ACCIDENTS AND EMERGENCIES**

Any accidents in which workers have been over-exposed to or contaminated with radioactive materials, or in which radioactive material has been spilled, need special action and the procedures set out in the authority

holder's internal rules must be followed. Each accident must be reported without delay to the RPO who in turn must report it to the regulatory authority, any accident involving radioactivity must be reported immediately to the RPO.

## **12. LIMITATION OF EXPOSURE TO RADIATION**

All exposure must be kept as low as is reasonably achievable, economic and social factors being taken into consideration. The exposure must therefore be so optimised that a further reduction in exposure would not be justified by the additional cost entailed.

The radiation dose to individuals must not exceed the effective dose limits laid down by the regulatory authority. These effective dose limits must be viewed as upper limits and must not be interpreted as being necessarily allowable. Furthermore, long-continued exposure of a considerable proportion of workers at or near the dose limits would be acceptable only if a careful analysis has shown that the results, resulting higher risk are justified.

It will be possible to achieve the above-mentioned goals only if all levels of contamination of work areas and air concentrations of radionuclides are kept as low as is practicable.

## **13. CALIBRATION OF MONITORING EQUIPMENT**

All equipment, including pocket dosimeters, used for the monitoring of radiation and contamination, must be regularly tested, and calibrated by an institution approved for the purpose (e.g., NMISA, or the SABS and NECSA), as required by the regulatory authority.

The equipment must be calibrated before being brough into use, after repair and at intervals not exceeding the following:

- (a) 7 months in the case of radiation monitors used for industrial radiography,
- (b) 14 months in the case of radiation monitors used for purposes other than industrial radiography, and
- (c) 26 months in the case of pocket dosimeters and direct reading dosimeters.

**NOTE:** It is even more important that monitors are checked as often as possible to ensure that their batteries are adequate, and they respond positively to radiation.

## **14. REFERENCES**

The following related documents are referenced:

- 14.1 The Hazardous Substances Act of 1973.
- 14.2 Regulations relating to Group IV Hazardous Substances, made in terms of section(s) 6 to 11, 25 and
  26 of the Hazardous Substances Act 15 of 1973 and published under Government Notice R247 in
  Government Gazette 14596, dated 26 February 1993 (R247).

## **15. VALIDITY**

This guideline is valid for a period of five years from the effective date of revision. It will be reviewed on this timeframe or as and when required.