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

31 January 2025

Approval of a dosimetry service in South Africa

This guideline sets out the requirements for the approval of a dosimetry service to operate in South Africa and provide passive monitoring of radiation workers.

Document History

Final Version	Reason for Amendment	Effective Date [dd Month yyyy]
1	First issue and published for implementation	Oct 2016
2	− Content structured on the new SAHPRA Guideline Template − A unique document number SAHPGL-RDN-XR-26 allocated to this Guideline	18 December 2024

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

Contents

Glossary

Abbreviation/ Term	Meaning
ADS	Approved dosimetry services
Hp (10)	Whole body dose equivalent (dose equivalent at 10 mm depth in tissue)
Hp (3)	Eye lens dose equivalent (dose equivalent at 3mm depth in tissue)
HP (0.07)	Skin dose equivalent (dose equivalent at 0.07 mm depth in tissue)
mSv	Milli-Sievert
NDR	National Dosimetry Register
NMISA	National Metrology Institute of South Africa
OSL	Optically stimulated luminescence
TLD	Thermal luminescence dosimeter
SANAS	South African National Accreditation System

1. INTRODUCTION

A dosimetry service provider may only operate in South Africa pursuant to Regulation 23 of the *Regulations relating to Group IV Hazardous Substances* (R247 of 1993) and Regulation III.5(c) of the *Regulations concerning the control of electronic products* (R1332 of 1973), after receiving approval from the Radiation Control Unit at the South African Health Products Regulatory Authority (SAHPRA). The purpose of approval is to ensure that a dosimetry service is technically competent and can assess doses with a reasonable degree of accuracy. To be approved, the dosimetry service must satisfy the criteria in Appendix A. These recommendations provide a basis for developing consistent and harmonized approval criteria for dosimetry services operating in South Africa.

1.1 Purpose

The purpose of these guidelines is to set out the criteria to entities that wishing to obtain approval to provide dosimetry service to licence holders approved in terms of the Hazardous Substances Act, 15 of 1973.

1.2 Scope

This guideline sets out requirements for dosimetry service providers to be approved and technical criteria for existing and new dosimetry service providers.

2. LEGAL PROVISION

The guidelines are implemented in accordance with the Hazardous Substances Act, 15 of 1973, and the related *Regulations concerning the control of electronic products* (R1332 of 1973). A dosimetry service provider may only operate in South Africa pursuant to Regulation 23 of the *Regulations relating to Group IV Hazardous Substance*s (R247 of 1993) and Regulation III.5(c) of the *Regulations concerning the control of electronic products* (R1332 of 1973).

3. APPLICATION FOR APPROVAL

3.1 Information to be submitted with Applications

A dosimetry service wishing to apply for approval in South Africa must apply in writing to SAHPRA Radiation Control.

- The following information should be included with applications:
- Full name and address of the dosimetry service and contact details.
- Scope for which approval is being sought.
- Approval in accordance with 3.1.2 below; Performance data from irradiation tests.

- Intercomparison exercises; Sample customer reports.
- Statement that the dosimetry service conforms to all of the Approval Criteria.
- Type test data (where appropriate)

3.1.1 Scope of Approval

The scope of approval should specify the type of dosimetry (internal, external whole body, external extremity, etc), the dosimeter technology (TLD, film, OSL, etc.), the dosimeter make and model, energy range, dose rate range and limitations or conditions for use.

3.1.2Evidence of Accreditation

The service shall provide a copy of their certificate and scope of accreditation to ISO 17025 issued by the South African National Accreditation System (SANAS) as a testing laboratory.

In the case of a dosimetry service whose processing is done outside of South Africa, the processing service shall provide a copy of their certificate and scope of accreditation to ISO 17025 and such accreditation must be recognised by SANAS. If, for example, the service (or a third party) runs a depot or distribution centre in South Africa it must demonstrate that these operations are covered by its quality system so that results cannot be adversely affected by that part of the operation.

3.1.3 Performance Data

The dosimetry service shall provide evidence of participation in recognized laboratory intercomparison. The application for approval should include performance data as follows:

- Evidence of regular satisfactory participation in intercomparisons
- Results of irradiation tests with a satisfactory response of the dosimetry system within the rated ranges of all input quantities as set out in the scope of approval.
- The results of intercomparison and irradiation tests must demonstrate compliance with accuracy of measurement of personal dose equivalents criteria set out in the technical criteria.
- SAHPRA Radiation Control may require that the applicant submit dosimeters for irradiation and performance testing

3.1.4 Sample Reports

The service shall provide samples of customer reports and guidance made available to customers.

3.1.5 Statement of conformance with approval criteria

The following declarations must be provided:

- The dosimetry service complies with SAHPRA Radiation Control's approval criteria.
- The reporting time in normal and accident situations shall comply with the response times set out in the technical criteria.
- The service will provide at least quarterly data to the National Dose Register (NDR) in a format specified by the National Dose Register Data Provider.

3.1.6 Type test data

In assessing an application for approval for a dosimetry system that is not of established and proven design, SAHPRA Radiation Control reserves the right to request that the applicant provide results of type testing against relevant international standards. For personal dosimeters to monitor individuals occupationally exposed to external radiation, several international standards exist for type testing as set out in Table 1 below. Such testing shall, where required, be undertaken by an independent laboratory internationally recognised as being competent to undertake such testing. In general, dosimetry systems which are already in widespread use will be of proven design.

Table 1: Dosimetry standards

Dosimetry Type	**Standard(s)**
Extremity TLD	ISO 12794
Whole body passive	IEC 62387-1
Personal and Environmental Monitoring	IEC61066
Direct reading dosimeters	IEC 61526

3.2 Assessment Process

Approval is granted to a dosimetry service following a satisfactory review of the documents submitted with the application to ensure that the criteria specified in Appendix A are met. The review will be carried out by SAHPRA Radiation Control and may include a member with expertise in personal dosimetry. SAHPRA Radiation Control reserves the right to include one or more external experts in the assessment team.

In assessing the applications, the assessment team will:

- Consider whether the type of dosimetry system as set out in the scope of approval is appropriate to its intended purpose.
- Consider if the scope of accreditation adequately covers the range of dosimetry systems/devices as set out in the scope of approval
- Consider if the performance data provided adequately demonstrates compliance with the *Technical*

recommendations for monitoring individuals occupationally exposed to external radiation (RP160).

- Consider if the sample reports comply with the requirements set out in the technical criteria.
- Consider if the declarations given are adequate. SAHPRA Radiation Control reserves the right to seek evidence to support these declarations.
- In assessing an application for approval for a dosimetry system, that is not of established and proven design, SAHPRA Radiation Control reserves the right to require the service to provide results of type testing against relevant international standards. In general dosimetry systems, which are not already in widespread use, will not be of proven design.

SAHPRA Radiation Control will not itself carry out on-site inspections of services or systems. Instead, SAHPRA Radiation Control will rely primarily on accreditation by SANAS to demonstrate that the service as delivered meets the technical specifications set out in the scope of approval. In assessing the applications., the SAHPRA Radiation Control assessment team will consider if the scope of accreditation adequately covers the range of dosimetry systems/ devices as set out in the scope of approval.

3.2.1 Incomplete application

If the information submitted is incomplete or unsatisfactory, the dosimetry service will be given the opportunity to submit additional information.

3.2.2 Approval

The approval specifies the dosimetry system together with details of the type of radiation(s) for which doses are assessed. If any changes are made to the dosimetry system including dosimeters or the type of radiation(s) for which doses are assessed a new application for approval must be submitted. Approval will remain valid provided that the dosimetry service must confirm annually, in writing, that they continue to comply with the approval criteria and maintain their SANAS accreditation as a dosimetry service provider.

3.2.3 Conditions of approval

Approval is granted with the condition that the dosimetry service must notify SAHPRA Radiation Control of any significant changes to the dosimetry system, any changes to approval in another country on which the initial application was based, or any changes to the service itself e.g. changes in key staff or location. Approval is also dependent on satisfactory performance data being submitted at regular intervals as specified by the SAHPRA Radiation Control.

3.2.4 Failure to receive approval

If an applicant is refused an approval, they will be notified of this decision by SAHPRA Radiation Control and advised of the areas in which they failed to meet the eligibility criteria.

3.3 Documentation to be provided annually

An approved dosimetry services must provide a declaration that they comply with the approval criteria annually. In the declaration the service must specify the date of the most recent intercomparison in which they participated. Intercomparison results received by the service since the last annual declaration should be provided.

3.4 Revocation of Approval

SAHPRA Radiation Control may revoke in writing any approval given to a dosimetry service. An approval may be revoked if an ADS:

- Does not conform to the current criteria for approval and fails to provide SAHPRA Radiation Control with an action plan which is sufficient to enable the deficiencies to be rectified within three months.
- Fails to provide evidence of on-going satisfactory performance in intercomparison tests which demonstrate that they continue to meet the relevant approval criteria.
- Persistently fails to report dose assessments for which it is approved within the period set out in the approval criteria.
- Fails to maintain SANAS accreditation.

In addition, where a serious complaint has been received, which is upheld following investigation by SAHPRA Radiation Control, the ADS approval may be revoked. SAHPRA Radiation Control may also revoke such approval where the ADS fails to cooperate with such an investigation.

3.5 Appeals

Applicants who have been refused approval or dosimetry services that have had their approval revoked have the right of appeal such revocation to the SAHPRA CEO in terms of Section 6 of the Hazardous Substances Act.

4. REFERENCES

1. Regulations concerning the control of Electronic Products- R.1332, 3 August 1973.
2. Regulations relating to Group IV Hazardous Substances - R.247 of 26 February 1993.
3. EC, 2009. Radiation Protection No 160, Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation. Luxembourg: European Commission.

5. VALIDITY

This document is valid for a period of five (5) years from the effective date of revision and replaces the GUIDELINES APPROVAL OF A DOSIMETRY SERVICE IN SOUTH AFRICA Rev1 Oct 2016. It will be reviewed in line with this timeframe or as and when required.

6. APPENDIX

6.1 APPENDIX A: Approved Dosimetry Service (ADS) – Technical Criteria and Customer Information

1. Scope of approval

The scope of approval shall specify the type of dosimetry (internal, external whole body, external extremity, etc), the dosimeter technology (TLD, film, OSL, etc.), the dosimeter make and model, energy range, dose rate range and limitations or conditions for use.

2. General

The service shall be able to demonstrate that it has the necessary administration, technical and quality systems to be able to provide and maintain a service that:

a) produces a reasonable degree of accuracy in the assessment of dose.

b) is highly reliable.

c) communicates the results of routine dose assessments to the customer within a reasonable time:

d) rapidly communicates to the customer the results of dose assessments made in the event of an accident, occurrence or incident.

3. Details of wearer and Organisation

3.1 Details of wearer

a) Surname, Full names

b) Nationality

c) If South African citizen, ID number must be used (copy of ID must be kept by ADS with personal information); if non-South African, a passport number should be used.

3.2 Organisation

a) Name of organisation

b) Physical address

c) Contact details

d) Contact person

e) Classification of organisation (Hospital, radiology, radiotherapy, mining, industrial radiography, etc.) (Align with SABS classification)

f) Licence/Authority number with SAHPRA Radiation Control

4. Dosimetry Methods

The assessment of individual doses shall be based on:

a) the issuance of individually identifiable personal dosimeters or other devices.

b) the processing of those dosimeters or devices.

c) the evaluation of the dose recorded by the dosimeters, or of the response of the devices; and

d) the assessment of the appropriate dose quantity for the individual for the relevant monitoring period.

The approval system covers only services which undertake all the above stages.

4.1 Identification of dosimeters

The service shall ensure that any dosimeter or other device it uses as part of the dosimetry system is of a readily identifiable type and model and can be shown by type testing and field trials to be suitable and reliable for the environments in which it will be used. Each dosimeter or device shall also be traceable to the individual to whom it is issued and the period of assessment.

4.2 Energy/dose ranges

The dose range for which approval is sought must be specified. In general, an appropriate dose range for a dosimeter used in the assessment of effective dose (E) would be 0.1 mSv to ~1 Sv for gamma/x-rays radiation and 0.2 mSv to at least 50 mSv for neutrons. An approved dosimetry service shall not offer a dose assessment service to a customer if the range of radiation energies likely to be encountered is broader than stated in the certificate of approval.

5. Traceability to National Metrology Institute of South Africa (NMISA)

The calibration of the dosimetry system can be shown to be traceable to NMISA or equivalent and the service shall be aware of the uncertainties associated with the calibration.

6. Irradiation tests

Performance tests shall be carried out for a representative number of dosimeters for each of several irradiation conditions to confirm that the overall accuracy is acceptable, and that the performance of the dosimetry system is as expected.

7. Intercomparison tests

Participation in national or international intercomparison exercises is a useful and necessary part of the performance test of a service. Approved services shall participate in a recognised independently organised intercomparison test at least once every two years.

The combined standard uncertainty for measurements of personal dose equivalents at the location of the dosimeter for gamma/x-rays and electrons shall not exceed ±30% for doses greater than 1 mSv for Hp (10) and 50 mSv for Hp (0.07) and ±20% or a factor of 1.5 at 95% confidence for doses near dose limits. The combined standard uncertainty for measurements of personal dose equivalents for neutrons shall not exceed ±50% for doses greater than 1 mSv for Hp (10).

If these limits are exceeded the dosimetry service is required to undertake a review and submit a report to SAHPRA Radiation Control with an action plan showing how the service intends to remedy the deficiency. A dosimetry service may be required to undertake another performance test to confirm that the improvement measures introduced have been effective.

8. Staff Competence

The service shall ensure that it has the necessary facilities and staff to carry out the measurement and assessment of individual doses. Adequate training programmes shall be available for new staff and refresher/update training for existing staff. Staff shall be free from any internal or external influence which could affect the quality or impartiality of their work. The responsibilities of key personnel shall be clarified to avoid conflicts of interest.

9. Data Handling

Procedures shall be in place for the safe handling, storage and back-up of records.

10. Accident preparedness

The service shall ensure that adequate arrangements are made for the timely despatch of dosimeters or other devices to customers and for the availability of sufficient and suitable dosimeter processing equipment appropriate to the scope of the service. Provision for breakdown of equipment, e.g. arrangements with the equipment supplier for routine maintenance, repair or temporary replacement of equipment, must be in place.

When the dosimetry service is notified by a customer of an incident, the service must have in place appropriate arrangements so that dosimeters can be returned, processed and the results made available within five (5) working days of despatch of the dosimeter from the customer's premises.

During routine processing, if a dose exceeds any relevant dose limit (see par. 13) it shall be reported to the customer as soon as the results are available e.g. by phone or email and followed up by written confirmation (see par. 13).

11. Reporting

In normal circumstances, every dose result shall be reported to the customer within 14 working days of receipt of the dosimeter. The report shall include the following information:

a) name and address of the ADS.

b) a unique report reference.

c) name and address of the customer.

d) wearer's first name and surname.

e) wearer's unique identification code.

f) dosimeter type, e.g. film, TLD, OSL, etc.

g) dosimeter identification code.

h) issue or wear period for each dosimeter (this shall be clearly defined in the report).

i) the position on the body where the dosimeter was worn e.g. trunk, left arm, etc.

j) *H*p (10), *H*p (0.07) or *H*p (3), as appropriate, recorded on the dosimeter and annual and/or 5-year accumulated dose.

k) signature of authorised member of staff.

l) a statement of measurement method and uncertainty.

m) the minimum reporting level.

n) the page number and the total number of pages in the report.

Where transit dosimeters are used to estimate the contribution to dose from natural background radiation, arrangements must be put in place to cover situations where the transit dosimeters are not returned for processing.

12. Reporting to SAHPRA Radiation Control

A dosimeter with a reading of 4 mSv or higher must immediately reported to SAHPRA Radiation Control and to the customer. The customer must be informed to complete form RC010 and to submit it to Radiation Control (###provide fax and email no ##). Similar process must be followed if the annual dose exceeds 20 mSv per annum for an individual.

13. Operational quantities

The operational quantities for personal monitoring, personal dose equivalent, *H*p (10), *H*p (3) and *H*p(0.07), shall be used as estimates of equivalent dose, HT and effective dose, E. For gamma/x-rays, in practical situations, *H*p (10) will provide a reasonable estimate of E. For doses near or above the dose limit, or above a fixed investigation level, it will be necessary to confirm that measurements of the operational quantities provide good estimates of the protection quantities. To determine effective dose, information is needed on both the energy and direction characteristics of the workplace field(s) and the position and orientation of the personal dosimeter. The customer may ask the dosimetry service, in conjunction with the Radiation Protection Advisor (RPA)/Responsible person, to assist in these cases.

The operational quantity *H*p (0.07) for gamma/x-rays and electrons is used for the assessment of dose equivalent to local skin. For neutrons, the use of dosimeters calibrated in terms of *H*p (10) would be appropriate. *H*p (3) may be estimated from measurements of *H*p (0.07) and *H*p (10). Alternatively, a simple design of dosimeter can be used, worn on the head, to directly estimate *H*p (3), comprising a skin dosimeter with additional covering. If a dosimetry service seeks approval for both the assessment of whole-body dose (or skin dose) and dose to the eyes, using the same type of dosimeter a case shall be made for such a purpose; and the written instructions to the customer shall cover both uses.

Where reliance is placed on the use of algorithms and correction factors to assess dose it is important to give a full explanation (by reference to type test data, etc.) to show that these are justified in the circumstances. Where algorithms are used, the dosimetry service shall state explicitly which algorithm will be used and under what circumstances, to avoid ambiguity. The values of any additional factors must also be stated explicitly.

14. Re-assessment and re-evaluation of doses

The service shall make reasonable arrangements to ensure that doses can be reassessed or re-evaluated up to two years after the receipt of a dosimeter (or another device), which shall include:

a) sufficient records to link any dose reported to the customer with a particular dosimeter worn, the method of evaluation of the dosimeter and the method of assessment.

b) a secure storage facility for the active elements of dosimeters such as film dosimeters; or

c) a facility to record and retain the output data retrieved from the dosimeter to assess the original exposure e.g. the glow curve output of TLDs; or

d) arrangements for independent diagnostic checks built into the dosimeter reader to ensure that the read-out is normal and where practicable is recorded for future reference; or

e) other equally effective means of re-evaluation.

The method used may depend on:

a) a re-examination of the original dosimeter; or

b) a re-examination of dosimeter outputs such as glow curves; or

c) reliability checks of the output during the read process,

together with a check of stored records relating individuals to the output for individual dosimeters and any special factors used (e.g. quality factors). Where appropriate, the service shall have arrangements for secure storage of exposed films/records to prevent loss e.g. in a fire.

15. Guidance made available to customers

The service shall provide advice to customers about the proper handling, storage, issue and use of the dosimeter or other device and any other information necessary to ensure that such dosimeters or devices are used correctly.

The advice to the customer would normally cover matters such as:

a) any limitations in the scope of approval such as energy restrictions and avoiding exposure to certain fields or environments.

b) recommended dosimeter issue and return procedures, including specific arrangements to ensure named persons are unmistakably linked to the dosimeters they wear.

c) location on the body where the dosimeter should be worn.

d) arrangements for dealing with unusual occurrences, e.g. late, damaged or lost dosimeters.

e) storage of dosimeters, including security against tampering and avoiding the risk of inadvertent exposure to ionizing radiations.

f) security against background radiation and any other environmental condition likely to affect the performance of the dosimeter adversely (this shall include reference to the potential for dosimeters to be passed through security scanning equipment which might affect the dosimeter reading).

g) correct assembly of dosimeters e.g. positioning of films/filters etc.

h) the warning period provided in active devices before battery failure.

i) special features or arrangements, e.g. remote reading of dosimeters/devices.

j) contamination monitoring of dosimeters (where applicable).

k) any special arrangements for handling dosimeters (or other devices) in the event of an accident, occurrence or incident.

The service shall provide advice, on request, on the suitability of their service in relation to the needs of the customer.

16. Unassessed doses

The dosimetry service shall not report a zero dose for components of dose that were not assessed, for example because a dosimeter was lost by the wearer or was not issued for a particular assessment period. A nominal dose of 4 mSv should be allocated.

17. Implementation of standards

Dosimetry systems shall be type-tested according to the relevant EN/IEC or ISO standard and shall have passed that test. All the radiation fields used must be well characterised and traceable to NMISA or equivalent.

18. Reporting of results to the National Dose Register (NDR)

The APD service shall provide at least quarterly data to the National Dose Register (NDR) in a format specified by the National Dose Register Data Provider.