South African Health Products
Regulatory Authority
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GUIDELINES FOR USERS OF ELECTRONIC THERAPEUTIC DEVICES EMITTING IONIZING RADIATION

This Guideline sets out requirements for radiation safety associated with the use of therapeutic devices emitting ionizing radiation.

The Hazardous substances Act, 1973 (Act 15 of 1973) and Regulations (No R1332 of 3 August 1973).

Document History

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CHIEF EXECUTIVE OFFICER

Contents

Glossary

Abbreviation/ Term	Meaning
ALARA	As low as reasonably achievable
DOH	Department of Health
Gy	Gray
HPCSA	Health Professions Council of South Africa
HSA	Hazardous Substances Act, 1973 (Act 15 of 1973)
IER	Individual equipment record
LINAC	Linear Accelerator
mSv	millisieverts
NDR	National Dose Register
NNR	National Nuclear Regulator
NCRP	National Council on Radiation Protection and Measurements
QA	Quality assurance
QC	Quality control
PDD	Percentage depth dose
PRMD	Personal radiation monitoring devices
SAHPRA	South African Health Products Regulatory Authority
SAMPS	South Africa Medical Physicist Society
SASQART	South African Standards for Quality Assurance in Radiotherapy

1. INTRODUCTION

This Guideline sets out requirements and recommendations for radiation safety associated with the use of Group III therapeutic devices emitting ionizing radiation. The Hazardous Substances Act 15, 1973 (HSA) and Regulations (No R1332 of 3 August 1973) govern the safe use of radiation therapy equipment in South Africa. Requirements of the Act and Regulations are incorporated in this Guideline.

Whenever compliance with a requirement in this Guideline is mandated, the word must/ shall be used. The word should indicate a recommended but not mandatory practice at this stage. Where a given technology or practice is not explicitly covered by this Guideline, guidance in matters of radiation protection should be sought from the SAHPRA (South African Health Products Regulatory Authority) Radiation Control Unit. The Licensee shall be responsible for ensuring that corrective action takes place on items of non-compliance with this Guideline. The HSA does not allow any person to use radiation equipment unless he/she holds a license under the HSA for that purpose. This Guideline must be read with the HSA and related regulations. All forms and guidelines are available at: https://www.sahpra.org.za/radiation-control-guidelines-and-codes-of-practice/.

1.1 Purpose

The purpose of this guideline document is to provide guidelines to users of therapeutic and particle accelerators to ensure the safe and effective use of equipment for intended purposes.

1.2 Scope

This guideline sets out requirements and recommendations for radiation safety associated with the use of radiation therapy and particle accelerators equipment for license holders of group III hazardous substances USE license.

2. LEGAL PROVISION

The guideline is implemented in promulgating the Hazardous Substances Act 15, 1973 (Act15 of 1973) the related Regulations R.1332. The holder shall be liable for the entire scope of radiation protection with regards to a listed electronic product or premises for which he holds a license. Such liability shall relate to any aspect that could reasonably be included under radiation protection, and, in addition to other relevant responsibilities which the SAHPRA may specify in the license, shall include:

i. Effective protection organization and continual conscientious regard for optimum working methods regarding routine operations.

ii. Technical reliability, maintenance and overall technical excellence of equipment, buildings, and infrastructure.

iii. The display of appropriate radiation warning signs or notices that are easily intelligible to all persons, at the entrances or at appropriate places in, where persons may enter and may be exposed to ionizing radiation.

iv. Ensuring that radiation workers and members of the public are subjected to minimal risks from radiation exposure, and that the maximum permissible doses and dose limits are not exceeded (refer to Section III.3. b. South African Hazardous Substances Act, 1973 (Act No. 15 Of 1973) and Regulations Relating to Group IV Hazardous Substances No. R. 1332, 1973).

3. LICENSING REQUIREMENTS

3.1 LICENSING OF THERAPEUTIC DEVICES

3.1.1 Regulations

The regulations concerning the Control of listed Electronic Products (R 1332) require that a joint product and premises license be obtained for radiation-emitting devices before it may be delivered, installed, accepted, and commissioned.

i. License issued in terms of Section IV (1) of the HSA shall apply only to the holder to whom the license was issued.

ii. Any license issued may be suspended or withdrawn by SAHPRA if:

- the holder or any of the licence holder radiation workers is found guilty of an offence in terms of these Regulations.
- the holder considers it in a case of emergency to be in the public interest.

iii. Any license issued in terms of Regulation II.2 shall remain in effect until request for cancellation, or temporary or permanent transfer thereof is approved by SAHPRA. If a license has been cancelled the holder shall return it to the SAHPRA within 30 days following the date of such cancellation.

iv. In addition to other relevant provisions, a license granted pursuant to Regulation II.2 shall clearly entitle the' holder to use a listed electronic product or licensed premises for a specified

purpose (see the HSA and related regulation R1332).

3.1.2 License application process

It is the responsibility of the prospective user of a therapeutic unit generating ionizing radiation to be in possession of a license from SAHPRA: Radiation Control prior to installation of the unit.

I. **New units (should use a latest Form No. GLF-RDN-XR-25D replacing old Form No. RC011 and a latest**

- The latest Form No. GLF-RDN-XR-25D (old Form No. RC011) application form is completed by the supplier and the end user of a new therapy unit completes the latest Form No. GLF-RDN-XR-25A (old Form No. RC003-1).
- The prospective user or supplier must request the latest Form No. GLF-RDN-XR-25D (old Form No. RC011 form from SAHPRA or can download the form from the SAHPRA website (https://www.sahpra.org.za/radiation-control-application-and-report-forms/).

II. **Form No. GLF-RDN-XR-25A (replacing old Form No. RC003-1)**

- For new units, section 12.1 of the latest Form No. GLF-RDN-XR-25A (old Form No. RC003-1) must be completed in full.
- The section applicable to the user must be completed and the form returned to the supplier. The supplier or user is responsible for submitting the completed form to Radiation Control for processing.

III. **Pre-owned unit's new forms (use the latest Form No. GLF-RDN-XR-25A replacing old Form No. RC 003-1 and a latest Form No. GLF-RDN-XR-25C replacing old Form No. RC003-3)**

- For new units, Section 12.2 of the latest Form No. GLF-RDN-XR-25A (old Form No. RC 003-1) must be completed.
- The latest Form No. GLF-RDN-XR-25A (old Form No. Form R C003-1) and the latest Form No. GLF-RDN-XR-25C (old Form No. RC 003-3) must be completed for a pre-owned therapy unit.
- It is the prospective user's responsibility to submit the completed application form (latest Form No. GLF-RDN-XR-25A (old Form No. RC 003-1) to Radiation Control.

- A completed and signed a latest Form No. GLF-RDN-XR-25C (old Form No. RC 003-3) from the previous owner must be submitted together with this latest Form No. GLF-RDN-XR-25A (old Form No. RC 003-1).

- Allow 30 working days (about six weeks) for processing applications.

3.1.3 Installations

The installation of a therapy unit may only commence after a license to "keep install" has been issued by SAHPRA as per condition 72. Newly constructed bunkers may be subjected to inspection prior to installation (see Section 11 of the latest Form No. GLF-RDN-XR-25A (old Form No. RC003-1)).

Application should be accompanied by a diagram or plan:

a. The normal location of the waveguide; the direction and extent of gantry movement; general direction(s) of the useful beam; locations of windows and doors; and the control panel's location.

b. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

c. The dimensions of the room(s) concerned.

d. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

e. Design dose levels for control and uncontrolled areas (see NCRP Report No. 151).

3.1.4 Radiotherapy equipment

In the provision of radiotherapy equipment, the Responsible Person is obliged to meet:

- The registration/ licensing criteria of the relevant regulatory authority.

- The Responsible Person should also ensure regular review of the equipment for safety and performance.

3.1.5 Acceptance tests and commissioning

Acceptance tests and commissioning must be performed prior to first clinic use of new and pre-owned equipment or post major upgrade/ service repair.

I. New Units

When a new unit is installed, acceptance tests must be performed by the manufacturer of the therapy or particle unit in the presence of the purchaser's appointed medical physicist. The results must be recorded on the prescribed document, signed off by license holder or by medical physicists on behalf of and filed in the IER of the unit.

II. Pre-owned units

The prospective user must ensure that acceptance tests are performed by a qualified medical physicist. Granting a license to use a unit is subject to submission of the acceptance tests results to SAHPRA: Radiation Control. When an existing licensed unit is moved to a new premises (building) or room, prior to use, acceptance tests must be performed on the unit and the results submitted to SAHPRA: Radiation Control.

NOTE: Units that have not been previously licensed by the SAHPRA: Radiation Control will not be licensed for use.

III. Commissioning

Commission of the linear accelerator is performed by a qualified medical physicist who must include comprehensive measurements of dosimetric parameters that are required by the treatment planning systems (TPS). The south African standards of quality assurance in radiotherapy (SASQART) prescribes frequencies of quality control tests to be performed in radiotherapy equipment. Medical physicists must ensure during commissioning that all tests comply with the requirements stated in SASQART guidelines.

3.1.6 Disposal or modification of therapy/ particle accelerator

i. The license holder must apply for and obtain permission from Radiation Control by submitting a completed form (latest Form No. GLF-RDN-XR-25C (old Form No. RC 003-3) prior to cancellation, modification, disposal and/ or sale of therapeutic equipment.

ii. Regarding the type of disposal, e.g., sale, dismantling, disappearance, or storage of a unit, it

must be furnished to SAHPRA: Radiation Control before the cancellation of the license will be affected.

iii. A disposal/ dismantling certification issued by a competent body must be obtained and forwarded to the regulator.

3.1.7 New/ modified premises (latest Form No. GLF-RDN-XR-25C, replacing old Form No. RC003-3)

The license holder must apply for and obtain permission prior to:

i. Modification of any licensed premises or layout of equipment on such premises, and/ or change of licensed premises (building) or equipment moved to other rooms within the same building.

3.1.8 Appointing of a medical physicist

i. A Medical Physicist must be appointed in writing by the License holder in pursuant of regulation R1332 section III.6.h and to establish and implement an optimization program for all radiation activities.

ii. An acting Medical Physicist must also be appointed in writing by the License holder and assumes the same responsibility when primary medical physicist is absent.

3.1.9 Appointing of Responsible person

The license holder must appoint a responsible person in pursuant of regulation R1332 section III.3.d. with adequate knowledge and experience in radiation protection. The appointed person is responsible to the license holder for the safe use of the therapeutic equipment (see also Section 3.2).

The person appointed must be qualified in either of the following categories and registered with the Health Professions Council of South Africa (HPCSA):

- Medical Physics, or
- Radiation Oncologist

The person responsible must be appointed in writing indicating the scope of the actions delegated by the license holder.

3.1.10 Change of responsible and of medical physicist

The license holder must notify Radiation Control of a change in responsible person by submitting a completed form (latest Form No. GLF-RDN-XR-25B, replacing old Form No. RC003-2).

3.2 RESPONSIBILITIES OF LICENSE HOLDERS / RESPONSIBLE PERSONS

3.2.1 The license holder of a radiation therapy facility is responsible for:

i. The entire scope of radiation safety, for the equipment and premises for which he/ she holds a license.

ii. Fulfilment of all related statutory requirements, and

iii. Compliance with the Act, Regulations and Conditions (condition 50, see **Annexure A** below) specified in the license.

3.2.2 Who Can be a license holder?

i. Executive manager of a private health Institution/ hospital with a Radiotherapy service

ii. Executive manager of s government health institution/ hospital with Radiotherapy service

3.2.3 The license holder/ responsible person must ensure that:

i. The equipment and the facilities in which such equipment is installed and used meet all applicable radiation safety standards.

ii. The equipment is maintained and functions properly.

iii. The equipment is used and maintained only by competent and appropriately trained people/ personnel.

iv. Applicable Quality Control (QC) tests are performed at the prescribed frequencies as stipulated in “SASQART and other International” documents.

v. The required QC equipment is provided.

vi. Ensure that radiation surveys to monitor safe performance of equipment and to monitor radiation levels in work areas are undertaken.

vii. All workers are appropriately qualified and registered with the HPCSA.

viii. Radiation workers (occupationally exposed persons) are identified and issued with personal radiation monitoring devices (PRMD's);

ix. The appropriate protective clothing, devices and equipment is provided to personnel and effectively used.

x. Radiation safety rules are communicated to and followed by all personnel.

xi. Operational procedures are established and maintained to ensure that the radiation exposure to workers, patients and public is kept as low as reasonably achievable (ALARA) without compromising the therapy efficiency of the result, and

xii. Workers are educated in the hazards and risks of ionizing radiation.

3.2.4 Employees Responsibilities

i. Employees should know and understand the regulations or standards set under act 15 of 1973 and your employer's operating and emergency procedures which apply to the employees' work.

ii. Employees should comply with these requirements for their own safety and the safety of others.

iii. Report promptly to their employer any condition which may lead to or cause a violation of these standards or employer's operating and emergency procedures.

3.2.5 Keeping of Patient Records

Records must be kept and available for inspection purposes by SAHPRA.

A record/ register must be kept of all patients undergoing radiotherapy treatments. The record/ register must be preserved for preserved for 5 years beyond the patient's lifetime and contain the following information:

- surname, name, date of birth or ID number/ age and gender, Identification photo.
- date of treatment.
- Treatment plan with following information: Number of radiation fields, Field sizes, maximum tumour dose (if applicable), minimum tumour dose (if applicable), and maximum tissue dose.

- Brief clinical indication of the examination.
- Treatment technique.
- Number of fractions and dose prescribed.
- Quality of radiation
- Radiation output of product (refer to the South African Hazardous Substances Act, 1973 (Act No. 15 of 1973) and Regulations Relating to Group IV Hazardous Substances No. R. 1332, 1973).

NOTE: For details on keeping patients records kindly refer to HPCSA Booklet 9 "Guidelines on the keeping of patient records."

3.2.6 Keeping of equipment records

Individual equipment records (IER) must be kept and contain all required information for a period of Five (5) years.

Such record may include:

- Preventative maintenance and service records
- Daily/Monthly /annual quality control tests
- Minor and major upgrade
- Calibration records after on regular basis or after repairs
- Isodose curves or percentage depth dose tables (PDD) and output factors

3.3 MINIMUM STAFFING LEVELS

Radiotherapy requires the involvement of a multidisciplinary team of professionals to execute the intent of the treatment. These professionals must include Radiation oncology, medical physicist, and radiation therapist. The International Atomic Energy Agency (IAEA) recommends an activity-based approach in ensuring radiotherapy practice has adequate staff (see Report No. 13, 2015). Radiotherapy departments should perform the calculation of staffing levels based on their activity to estimate the adequate required staffing levels.

The license holder must always ensure that there is enough of the following personnel:

3.3.1 Radiation Oncologist (RO)

The Health Professions Council of South Africa (HPCSA) stipulates the training requirements, and candidates complete the relevant 4-year curriculum of the College of Radiation Oncologists of SA. Candidates undergo training in a HPCSA-accredited training unit in a teaching hospital.

3.3.2 Medical Physicist (MP)

A person who is registered as such by the Health Professional Council of South African (HPCSA) and whose certificate of registration as a medical physicist with the Council has been endorsed to the effect that he is competent to practice as a radiation medical physicist. The scope of a medical physicist is published as regulation No. R. 310 of 26 February 1988 in terms of section 33(1) of the medical, Dental and Supplementary Health Service Profession Act, 1974 (Act 56 of 1974). Sufficient number of medical physicists must be retained as specified in the latest document of South African Medical Physicist (SAMPS), see **Annexure B** below.

3.3.3 Radiation Therapy Therapist (RTT)

The person administering accurate radiation treatment to a patient for radiotherapy treatment, care of patients, and is the person who fulfils the role of operator. This will usually be a qualified Radiation Therapist as published under Government Notice No. R. 2326 in Government Gazette 5349 of 3 December 1976 is hereby repealed. (Act No. 56 of 1974).

3.3.4 Qualified personnel

The license holder should ensure that all tasks directly related to the servicing and maintenance of radiotherapy equipment, and the planning and delivery of radiotherapy, should be performed by appropriately qualified and trained personnel. (Regulation that supports?).

3.4 PREMISES REQUIREMENTS

3.4.1 Bunker Design

The shielding of an external beam radiation therapy facility shall be designed according to the recommendations of United States (US) National Council on Radiation Protection and Measurements (NCRP, Report No. 151 of 2005).

3.4.2 Radiation Warning Signs, Notices and Lights at entrances to X-ray rooms.

Appropriate radiation warning signs and notices must be displayed and required warning lights (Green and Red) in working order: (a) Fixed units: A radiation warning sign and warning notice, "X-RAYS NO

UNAUTHORISED ENTRY" must be displayed at all entrances leading to the rooms where x-ray units are installed.

3.5 RADIATION PROTECTION

3.5.1 Dose limits for radiation workers and public

Every license holder must provide a personal radiation monitor/ dosimeter from a SAHPRA approved Dosimetry Service to all employees who are categorised as radiation workers and must be worn during working hours. (R1332) Wearing period for the personal radiation monitor is the period that a specific dosimeter should be worn by a specific radiation worker. There are 13 wearing periods of 28 days in a year and if required a wearing period can be 14 (fourteen) days for workers with a higher risk of exposure (SABS, 2016). The personal radiation monitor must be replaced by Dosimetry Service at regular intervals not exceeding 32 days and whenever a radiation occurrence is suspected (refer to the South African Hazardous Substances Act, 1973 (Act No. 15 of 1973) and Regulations Relating to Group IV Hazardous Substances No. R. 1332, 1973).

It should be recognised that these dose limits represent the boundary between unacceptable doses and doses that are tolerable. Thus, the aim is to keep individual doses as low as reasonably achievable (ALARA), economic and social factors being considered (see the Table 1 below).

Table 1: Dose limits in accordance with the international commission on Radiological Protection.

Application	**Occupational**	**Public**
Effective dose	20 mSv per annum, not more than 100 mSv over a period of 5 years (not more than 50 mSv in any one year)	1 mSv per annum
Annual equivalent dose to the: lens of the eye Skin hands and feet	 20 mSv 500 mSv 500 mSv	 1 mSv 50 mSv

Please Note: Additional restrictions apply to the above-mentioned occupational dose limit of pregnant women. When pregnancy has been diagnosed, the conceptus must be protected by applying a supplementary equivalent dose limit to the surface of the woman's abdomen (lower trunk) of 2 mSv for the

remainder of the pregnancy (see South African Hazardous Substances Act, 1973 (Act No. 15 of 1973) and Regulations Relating to Group IV Hazardous Substances No. R. 247).

3.5.2 Approved dosimeter services.

i. The license holder must ensure that all the registered radiation workers are issued with personal radiation monitoring devices (PRMD).

ii. Application forms for PRMD's can be obtained directly from the following approved Radiation Protection Service Provider(s):

Name of SERVICE	***Contact No.***	***Email address***
SABS Holdings	012 428 6199	rps@sabs.co.za
Dosimeter Services (Pty) Ltd	012 677 8074	admin@dosimeterservices.co.za

iii. Records of the radiation doses to which workers have been exposed will be furnished to the license holder by the SABS monthly or after a radiation occurrence (see 3.5.3 below). The records must be kept for 10 years.

iv. National Dose Register (NDR) managed by National Nuclear Regulator (NNR) will be available and records will be accessed by using an identity number (ID).

3.5.3 Occupational Radiation overexposures using GLF-RDN-XR-10A (old Form No. RC010)

i. Details of any radiation occurrence or suspected radiation occurrence involving radiation workers must immediately be reported to SAHPRA radiation control on form GLF-RDN-XR-010A (old Form No. RC010).

ii. The workers concerned must immediately submit their personal dosimeters to the dosimetry service provider. The license holder must liaise with Radiation Control on what action is to be taken after such occurrence.

iii. Occupational radiation overexposure of over 4mSv per wearing period must be reported to SAHPRA radiation control on the latest Form No. GLF-RDN-XR-010A (old Form No. RC010).

3.5.4 Reporting of Incidents/ Occurrences

The license holder shall ensure that all suspected radiation incidents are immediately reported to SAHPRA: Radiation Control As stipulated in Condition 50 (see appendix 2). A "radiation occurrence" means a single event or series of events occurring during the use of a listed electronic product which has resulted in injurious or potentially injurious exposure of any person to ionising radiation as a direct result of the use of that product. The license holder must investigate the circumstances of the exposure, the possible effects on a person(s) concerned and decide on the action to be taken. The outcome of this investigation must be documented (refer to South African Hazardous Substances Act, 1973 (Act No. 15 of 1973) and Regulations Relating to Group IV Hazardous Substances No. R. 247).

3.6 INSPECTIONS (PRE & ROUTINE)

SAHPRA radiation control will conduct a pre inspection followed by inspecting the workplace from time to time to ensure that health and safety requirements are being followed and that these requirements are effective in protecting the public and workers. The routine inspection frequency of the facility shall be 2 years.

4. REFERENCES

The following related documents are referenced:

4.1 HPCSA. (2016). *Guidelines for good practice in the Health Care Proffesions.* Pretoria: Health Professions Council of South Africa.

4.2 ICRP. (1991). *Recommendations of the International Commission on Radiological Protection, ICRP 60.*

4.3 NCRP. (2005). *Report No 151, Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities.* Bethesda: National Council on Radiation Protection and Measurements.

4.4 REPORTS NO.13, I. H. (2015). *STAFFING IN RADIOTHERAPY: AN ACTIVITY BASED APPROCH.* VIENA: IAEA.

4.5 SABS, R. P. (2016, 05 02). *General information on the use of personal dosimeters.* Retrieved 12 05, 2022, from http://radiationsafe.co.za/wp-content/uploads/2016/05/2.2.2-RPS-SABS-general-information-use-and-types-must-be-UPDATED.pdf

4.6 South, A. (1973). *HAZARDOUS SUBSTANCES ACT, 1973 (ACT No. 15 OF 1973) REGULATIONS RELATING*

TO GROUP IV HAZARDOUS SUBSTANCES. Pretoria: Department of Haalth.

4.7 South, A. (1973). *HAZARDOUS SUBSTANCES ACT, 1973 (ACT No. 15 OF 1973) REGULATIONS RELATING TO GROUP IV HAZARDOUS SUBSTANCES No. R. 1332.* Pretoria: Government Gazette.

4.8 South, A. (1973). *Hazardous Substances Act, 1973 (Act of 15 of 1973).* Retrieved 12 03, 2022, from https://www.sahpra.org.za/radiation-control-acts-and-regulations/

4.9 South, A. (1974). *HEALTH PROFESSIONS ACT, 1974 (ACT No. 56 OF 1974) REGULATIONS DEFINING THE SCOPE OF THE PROFESSION OF RADIOGRAPHY.* Pretoria: Department of Health.

4.10 South, A. (n.d.). *HAZARDOUS SUBSTANCES ACT, 1973 (ACT No. 15 OF 1973) REGULATIONS RELATING TO GROUP IV HAZARDOUS SUBSTANCES No. R. 247.* Pretoria: Government Gazette.

5. VALIDITY

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

6. ANNEXURES

6.1 Annexure A: Condition 50

The license holder shall ensure that:

a. All the applicable quality control tests are performed at the prescribed frequencies as specified in the SASQART guidelines that are available at https://sites.google.com/site/radiationcontroldoh/ -> Electronic Devices ->Ionising Radiation -> Radiotherapy.

    i. These tests are documented as prescribed in the SASQART guideline, and

    ii. All tests comply with all the requirements as prescribed in the applicable SASQART guideline.

b. At all times the services of a sufficient number of medical physicists are retained to ensure that optimal technical support and supervision are available to provide for effective patient, operator and public protection. "Sufficient number of medical physicists" means the number of medical physicists as specified in the latest document of SAMPS that is available at: https://sites.google.com/site/radiationcontroldoh/-> Electronic Devices -> Ionising Radiation -> Radiotherapy -> Minimum Staffing Levels for Radiation Oncology Physicists.

c. No radiation therapist operates a radiation oncology treatment unit for patient treatment without a second radiation therapist or a medical physicist or a radiation oncologist being present to verify treatment parameters.

d. Dose verification, applicable to the relevant technology and deemed by the resident medical physicist to be an acceptable form of verification, is performed on all patients receiving megavoltage photon therapy within 7 days after the first fraction or before 20% of the total prescribed dose has been delivered (whichever is sooner). Deviations of more than 10% from the calculated dose must be reported to the medical physicist immediately.

e. A comprehensive quality management system for radiation safety has been compiled and protocols, procedures, policies, instructions, tests, evaluations and rules are performed and documented in accordance with the system. This local system must include, but not limited to, the chart check protocol, the roles and responsibilities of the respective members of the radiation oncology team and the peer review mechanisms in place.

f. Independent verification of the results of quality control tests is an essential component of any quality control program. To ensure redundancy and adequate monitoring, a second qualified medical physicist must independently verify the implementation, analysis and interpretation of the quality control tests at least annually. This independent check must be documented.

g. All suspected radiation occurrences are immediately reported to the Director: Radiation Control. A "radiation occurrence" means a single event or series of events occurring in the course of the use of a listed electronic product which has resulted in injurious or potentially injurious exposure of any person to ionising radiation as a direct result of the use of that product. The responsible person and medical physicist must investigate the circumstances of the exposure, the possible effects on a person(s) concerned and decide on the action to be taken.

6.2 **Annexure B:** SAMPS-Minimum Staffing levels MP

SOUTH AFRICAN MEDICAL PHYSICS SOCIETY

SUID-AFRIKAANSE MEDIESE FISIKA VERENIGING

021 - 9443804 Cape Gate Oncology Centre, P.O. BOX 15531, Panorama, 7506, SOUTH AFRICA
E-MAIL: liebner.koen@cancercare.co.za
WEB: http:/www.saapmb.org.za/samps/

02 April 2012

Att: Mr E Smit
Directorate of Radiation Control
Department of Health
Private Bag X62
7535
BELLVILLE

MINIMUM STAFFING LEVELS FOR MEDICAL PHYSICISTS RENDERING A SERVICE IN RADIATION ONCOLOGY

The proposal by a SAMPS working group has been accepted by the SAMPS executive regarding revision of the 2007 recommendations of minimum staffing levels for Medical Physicists rendering a service in Radiation Oncology.

The revised recommendations are as follows:

1. One (1) full time equivalent Medical Physicist should attend to Medical Physics duties for every 600 patients receiving radiation therapy.

   The ratio of 1 to 600 escalates the ratio of 1 to 800 that was adopted by SAMPS in 2007. The stricter requirement could be justified by the increase in availability of qualified medical physicists observed in the past 10 years. The ratio of 1 to 600 will also bring South Africa closer to the IAEA recommended ratio of 1 to 400.

2. A further revision of the recommendations could be considered in future with the objective to implement a more sophisticated system such as the criteria applied by the European Federation of Organisations for Medical Physics (EFOMP) policy statement: "*Criteria for the staffing levels in a Medical Physics Department*", *September 1997*.

Yours Sincerely

Graeme L Lazarus
Chairperson: South African Medical Physics Society