

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

29 August 2022

IONIZING RADIATION DOSE LIMITS AND ANNUAL LIMITS ON INTAKE OF RADIOACTIVE MATERIAL

Dose limits are intended to reduce the risk of serious effects occurring, such as cancer, and are in place to
protect the eyes, skin, and extremities against other forms of damage.

Document History

Final Version	Reason for Amendment	Effective Date
0	First issue and published for implementation	July 2001
1	 Content structured on the new SAHPRA Guideline Template A unique document number SAHPGL-RDN-XR-15 allocated to this Guideline 	September 2022

DR BOITUMELO SEMETE-MAKOKOTLELA CHIEF EXECUTIVE OFFICER

SAHPGL-RDN-XR-15_v1 Page 1 of 11

Contents

Doc	ument History	1
Glos	sary	3
1.	INTRODUCTION	4
1.1	Purpose	4
1.2	Scope	4
2.	LEGAL PROVISION	4
3.	DOSE LIMITATION	5
3.1	A system of dose limitation is laid down whereby:	5
4.	OCCUPATIONAL EXPOSURE	5
4.1	Effective Dose Limit	5
4.2	Non-uniform Exposure	6
4.3	Equivalent Dose Limits	6
4.4	Annual Limits on Intake	6
4.5	Rates of Dose Accumulation	6
4.6	Previous exposure unknown	7
4.7	Exposure of women of reproductive capacity	7
4.8	Exposure of pregnant women	7
4.9	Abnormal exposures	7
4.10	Potential exposures	8
5.	CLASSIFICATION OF WORKPLACES AND DOSIMETRY	8
5.1	Controlled Areas	8
5.2	Supervised Areas	8
5.3	Personal Dosimetry	8
6.	PUBLIC DOSE LIMITS	9
7.	SUMMARY OF DOSE LIMITS	9
8.	REFERENCES	10
9.	VALIDITY	10
10.	ANNEXURES	11
10.1	Annexure A: Effective dose in sievert (Sv), previously termed the effective dose equivalent	11

Glossary

Abbreviation/ Term	Meaning
ALI	Annual limits on intake
DAC	Derived Air Concentrations
EDL	Effective Dose Limits
ICRP	International Commission of Radiological Safety
mSv	Milli-Sieverts
Deterministic effects	(previously termed non-stochastic effects) Are those for which the severity of the effect varies with the dose, and for which a threshold may therefore occur, for example, lens opacification, or loss of function of other organs.
Effective dose in sievert (Sv)	(previously termed the effective dose equivalent) Is the sum of the weighted equivalent doses in all the tissues and organs of the body. The weighting factor to be used is the tissue weighting factor, wT. A uniform equivalent dose to the whole body gives an effective dose numerically equal to that uniform equivalent dose. If the equivalent dose to an organ with weighting factor wT is HT, the effective dose is given by:
Medical exposure	Refers to the exposure of patients during medical procedures and not to the exposure of the personnel conducting or incidentally associated with such procedures.
Stochastic effects	Are those for which the probability of an effect occurring, rather than its severity, is regarded as a function of dose. Stochastic effects include somatic effects (such as fatal or non-fatal cancers occurring in exposed individuals) as well as hereditary effects (effects transmitted to future generations).

SAHPGL-RDN-XR-15_v1 Page 3 of 11

1. INTRODUCTION

The dose limits and annual limits on intake of radioactive material (ALI) laid down by SAHPRA: Radiation Control are based on the recommendations of the International Commission on Radiological Protection in ICRP Publication 60 (ref. 1) and ICRP Publication 61 (ref. 2) respectively. These limits are intended to prevent deterministic effects and to limit the occurrence of stochastic effects to an acceptable level.

When calculating the total accumulated effective dose to an individual, exposure from both internal and external radiation sources must be considered. The effective dose limit (EDL) is therefore supplemented by a secondary limit, the annual limit on intake (ALI), to take cognizance of exposures due to the intake of radioactive material. An effective dose E from external exposure and intakes leading to internal exposure must satisfy the following equation for the specified period:

$$\frac{E}{EDL} + \sum_{i} \frac{I_{j}}{ALI_{j}} \le 1$$

In practice, this situation is unlikely to arise, and the control of radiation exposure will usually be based on either external exposure or internal exposure and not on a combination of both. For the purposes of implementing the dose limits, SAHPRA: Radiation Control will, apart from this directive, from time-to-time issue directives about derived limits (such as derived air concentrations), occupationally related dose constraints, or other reference levels (such as recording levels, investigation levels, intervention levels, etc.).

1.1 Purpose

Dose limits are set to protect workers and members of the public from the effects of ionizing radiation. They are set at a level that balances the risk from exposure with the benefits of using ionizing radiation.

1.2 Scope

This guideline contains dose limits and annual limits on the intake of radioactive material and describes how to calculate the total accumulated effective dose to an individual exposed to ionizing radiation after the intake of radioactive material.

2. LEGAL PROVISION

The Hazardous Substances Act, 1973 (Act 15 of 1973) and Regulations R247 relating to Group IV Hazardous Substances R.247 of 26 February 1993.

SAHPGL-RDN-XR-15_v1 Page 4 of 11

3. DOSE LIMITATION

3.1 A system of dose limitation is laid down whereby:

- No practice involving exposures to radiation shall be adopted or continued unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes;
- All exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure shall be constrained by appropriate restrictions on the doses to individuals; and
- c. The doses to individuals shall not exceed the limits laid down in this directive. The dose limits represent the upper bounds of acceptability and should not necessarily be interpreted as allowable limits.
 - With regard to (b) above it should be noted that the requirement of keeping doses as low as is reasonably achievable (optimization of protection) is particularly important and that individual exposures, even below the level of the dose limits, are not necessarily acceptable, if judged in the light of this requirement. Source-related individual dose constraints (below the dose limits) must be applied, to ensure adequate protection of the individual. Continued exposure of workers at or near the dose limits will only be acceptable if a careful analysis has shown that the associated risk is justifiable.
- d. Doses resulting from natural background and from medical exposures are generally excluded from the dose limits referred to in paragraph 7 unless SAHPRA: Radiation Control deems it necessary, in any particular case, to include exposure from natural radioactivity in a workplace.
- e. The dose limits cover two categories of exposed individuals:
 - (i) Occupationally exposed individuals (i.e. adults exposed in the course of their work), and
 - (ii) Members of the public.

4. OCCUPATIONAL EXPOSURE

4.1 Effective Dose Limit

To limit the occurrence of stochastic effects, the effective dose to a worker may not exceed 20 mSv (2 rem) per year, averaged over 5 years (100 mSv in 5 years), with a further provision that the effective dose may

SAHPGL-RDN-XR-15 v1 Page 5 of 11

not exceed 50 mSv in any single year.

The above dose limit must be applied to all occupational exposure and must include that resulting from minor mishaps and misjudgments in operations and from maintenance and decommissioning in circumstances not necessarily envisaged by the designers. This represents a significant increase in the stringency of the limits, regardless of the change in magnitude thereof.

4.2 Non-uniform Exposure

In the case of non-uniform or partial exposures, account must be taken of the contribution of different organs to the overall stochastic effects on the body. The effective dose E must then be calculated with the use of tissue weighting factors, representing the contribution from different organs or tissues (see Annexure A, below).

4.3 Equivalent Dose Limits

The restriction on effective dose specified in sub-paragraph 4.1 is sufficient to ensure the avoidance of deterministic effects in all body tissues and organs except the skin and the lens of the eye. Additional equivalent dose limits are needed for these tissues. The annual limits are 20 mSv for the lens of the eye and 500 mSv for the skin averaged over any 1 cm2, regardless of the area exposed. The latter limit is also applicable to the hands and feet.

4.4 Annual Limits on Intake

Annual limits on intake (ALI's) for several radionuclides are given in ICRP Publications 61. These ALI's are based on a committed effective dose of 20 mSv. Estimated intakes may be averaged over a period of 5 years to provide some flexibility. Where necessary, the intake of nuclides must be added to the external exposure, as described on page 1.

The ALI values are frequently used to find derived levels of concentrations of radionuclides for the purpose of implementing control measures in practice. In this way, Derived Air Concentrations (DAC) are found which describe those concentrations of radionuclides in air which, when inhaled during normal working hours for one year, will lead to the annual limit of intake (ALI). In a similar fashion, taking cognizance of the mode of intake, other concentrations can be established in particular situations that could lead to the ALI.

4.5 Rates of Dose Accumulation

No further restriction is placed on the instantaneous rate or the rate at which the equivalent dose may be accumulated, except in the case of pregnant women. However, it is advisable that the management of an

SAHPGL-RDN-XR-15_v1 Page 6 of 11

institution implement such restrictions from the point of view of administrative control.

4.6 Previous exposure unknown

If the previous exposure cannot be derived conclusively, it shall be assumed that the worker has received a dose equal to the currently recommended equivalent dose limit (20 mSv) in each year of any given period.

4.7 Exposure of women of reproductive capacity

The prescribed dose limits for the control of the occupational exposure of women who are not pregnant are the same as those for men. No special requirements are necessary.

4.8 Exposure 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 and by limiting intakes of radionuclides to less than 1/20 of the ALI. Arrangements should be made to ensure that the pregnant woman performs work that is of a type that does not carry a significant probability of high accidental doses and intakes.

4.9 Abnormal exposures

Doses received under abnormal circumstances should be recorded together with, and clearly distinguished from, normal exposures.

a. Emergency exposures

Exposures in excess of the recommended dose limits are acceptable in operations during or immediately after an emergency, to save a life, to prevent injuries, or to prevent a substantial increase in the scale of the incident. Such exposures are voluntary and should not exceed 0.5 Sv, except for life-saving actions. The equivalent dose to skin should not exceed 5 Sv, again except for life-saving actions. Once the emergency is under control, remedial work must be treated as normal occupational exposure.

b. Accidental exposures

Accidental exposures in excess of the limits recommended for normal practice differ from emergency exposures in that they are unavoidable and unforeseen. For this reason no dose limits are set for such exposures. Levels must be limited by equipment design, protective features and the provision of emergency procedures.

SAHPGL-RDN-XR-15_v1 Page 7 of 11

If a dose or intake of radioactive material exceeds twice the annual limit, the situation should be reviewed by the appointed doctor.

4.10 Potential exposures

Dose limits do not apply directly to potential exposures. For potential exposures, risk limits (which take account of both the probability of incurring a dose and the detriment associated with that dose), rather than dose limits, should be applied. In addition, the detriment associated with possible intervention (should the event occur) should be taken into account. ICRP 60 should be consulted in this regard.

5. CLASSIFICATION OF WORKPLACES AND DOSIMETRY

In order to facilitate the control of occupational exposure, workplaces containing sources of radiation must be formally designated as controlled or supervised areas, the aim being to ensure that anyone outside the designated areas need not be regarded as occupationally exposed. The designation should be based on operational experience and judgement, and must take account of the expected level and likely variations of doses and intakes, as well as the potential for accidents.

5.1 Controlled Areas

A controlled area is one in which normal working conditions, including the possible occurrence of minor mishaps, require the workers to follow well-established procedures and practices aimed specifically at controlling radiation exposures.

5.2 Supervised Areas

A supervised area is one in which the working conditions are kept under review, but special procedures are not normally needed.

5.3 Personal Dosimetry

All occupationally exposed workers should be subject to individual monitoring for external radiation unless their doses will be consistently low or, as in the case of air crew, it is clear that the circumstances prevent the doses from exceeding an identified value.

Individual monitoring for intakes of radioactive material is usually much more difficult, and should be used routinely only for workers who are employed in areas that are designated as controlled areas specifically in relation to the control of contamination and in which there are grounds for expecting significant intakes.

SAHPGL-RDN-XR-15_v1 Page 8 of 11

6. PUBLIC DOSE LIMITS

- 6.1 The scope of dose limits for public exposure is confined to the doses incurred as a result of practices. Situations which can only be influenced by intervention (e.g. radon in dwellings and in the open air, radioactive materials, natural or artificial, already in the environment, and other natural sources) are thus excluded.
- 6.2 No member of the public may receive more than 1 mSv in a year. However, in special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year.
- 6.3 In addition, no member of the public may receive an equivalent dose of more than 1 mSv to the lens of the eye and 50 mSv to the skin, averaged over 1 cm2, regardless of the area exposed.

7. SUMMARY OF DOSE LIMITS

	OCCUPATIONAL	PUBLIC
APPLICATION	DOSE LIMIT	DOSE LIMIT
Effective Dose	* 20 mSv per year,	** 1 mSv per year
	averaged over 5 years,	
	and not more than 50	
	mSv in any 1 year.	
Annual Equivalent Dose to:		
Lens of the eye	20 mSv	1 mSv
skin	500 mSv	50 mSv
hands and feet	500 mSv	-

^{*} Additional restrictions apply to the exposure of pregnant women (see paragraph 4.8)

SAHPGL-RDN-XR-15_v1 Page 9 of 11

^{**} In exceptional cases, this may be exceeded provided that the average over 5 years is less than 1mSv per year.

8. REFERENCES

The following related documents are referenced:

- 8.1 Guideline for Personal Monitoring Med and Vet Use of Diagnostic X-Ray Equipment https://www.sahpra.org.za/document/guideline-for-personal-monitoring-med-and-vet-use-of-diagnostic-x-ray-equipment/
- 8.2 ICRP (1991). 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication 60, Annals of the ICRP 21(1-3), Pergammon Press, Oxford.
- 8.3 ICRP (1991). Annual Limits on Intake of Radionuclides by workers Based on the 1990 Recommendations, ICRP Publication 61, Annals of the ICRP 21(4), Pergammon Press, Oxford.

9. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old guideline for Ionizing Radiation Dose Limits and Annual Limits on Intake of Radioactive Material DLUG91-1, revised July 2001. It will be reviewed on this timeframe or as and when required.

SAHPGL-RDN-XR-15_v1 Page 10 of 11

10. ANNEXURES

10.1 Annexure A: Effective dose in sievert (Sv), previously termed the effective dose equivalent

$$E = \sum_{T} w_{T}.H_{T}$$

Values of \mathbf{w}_T are given in the following table:

0.20
0.12
0.12
0.12
0.12
0.05
0.05
0.05
0.05
0.05
0.01
0.01
0.05

For further details of calculations consult ICRP publication 60 (ref. 1). Equivalent Dose in sievert (Sv) is the absorbed dose (in gray) averaged over a tissue or organ and weighted for the relevant radiation quality. The equivalent dose in tissue T is given by the expression:

$$H_T \sum_R w_R. D_{T,R}$$

where $D_{T,R}$ is the absorbed dose averaged over the tissue or organ T, due to radiation R and wR is the radiation weighting factor (previously called quality factor).

Values of w_R are given in the following table:

Photons (e.g. Gamma and X-radiation):	1
Muons and Electrons (e.g. Beta Radiation):	1
Neutrons less than 10 keV:	5
Neutrons 10keV-100 keV:	10
Neutrons more than 100keV-2 MeV:	20
Neutrons more than 2 MeV-20MeV:	10
Neutrons more than 20 MeV:	5
Protons, other than recoil protons, energy > 2MeV:	5
Alpha Particles, fission fragments, heavy nuclei:	20

SAHPGL-RDN-XR-15_v1 Page 11 of 11