Queensland Government

Radiation Safety Act 1999

RADIATION SAFETY STANDARD NM012:2010

Standard for radiation apparatus used to carry out sterilisation

Preface

Under section 17 of the *Radiation Safety Act 1999*, a possession licensee who, under a licence, possesses an ionising radiation apparatus to carry out a radiation practice, must ensure that the apparatus is not used for this purpose, unless the radiation apparatus complies with the relevant standard.

This radiation safety standard NM012:2010 *Standard for radiation apparatus used to carry out sterilisation* is made under section 16 of the *Radiation Safety Act 1999*.

This standard sets the minimum safety criteria for radiation apparatus used to carry out sterilisation. Compliance with this standard will assist in ensuring that public and occupational exposure to radiation is minimised.

Queensland Health has prepared this standard based on information derived from reputable sources such as the National Health and Medical Research Council.

The standard will be reviewed periodically to re-evaluate its currency and its appropriateness as the standard for radiation apparatus used to carry out sterilisation.

By ensuring compliance with this radiation safety standard, radiation protection around radiation apparatus in Queensland will continue to be in accordance with the high standard for radiation apparatus set in this State for many years.

I, Paul Lucas, Deputy Premier and Minister for Health, pursuant to section 16(1) of the *Radiation Safety Act 1999*, make the radiation safety standard NM012:2010 *Standard for radiation apparatus used to carry out sterilisation*, for the purposes of the Act.

SIGNED

PAUL LUCAS MP
Deputy Premier
Minister for Health

19 / 08 / 2010

Contents

Standard for radiation apparatus used to carry out sterilisation

Section 1 – General

1.1 Scope

This radiation safety standard sets out the minimum requirements for ionising radiation apparatus that is used to carry out sterilisation

1.2 Expiry

This radiation safety standard expires on 1 September 2020.

1.3 Documents

Documents which may provide some useful information are listed in Appendix A.

1.4 Definitions

In this standard -

“irradiation room” means a room, facility or premises where a radiation source is energised or used to carry out a radiation practice or where radioactive substances are stored.

"machine source" means a radiation apparatus producing electrically generated ionising radiation.

"machine source irradiator" means an irradiator, incorporating a machine source; the ionising radiation is produced within an irradiation room which is maintained inaccessible during use by interlocked controls.

“radiation dose rate” means the amount of energy from radiation absorbed by the person or thing exposed to the radiation during a particular time.

"radiation level" means the air kerma radiation dose during a specified time.

"radiation shield" means the material which has as its primary function the attenuation of radiation emitted by the radiation source to acceptable levels.

Section 2 – Standard - Machine source irradiators

Test	Compliance Test	Criteria for Passing the Test
Operating parameters		
1	Control console	Provision must be made for the adjustment and display, at the control console, of operating parameters which determine the energy of the primary beam, the radiation dose rate, exposure duration and any other parameters which influence the radiation dose received by the product being irradiated.
2	Control label	The control panel or console must be easily identifiable as being part of the irradiator. Each control must be clearly and unambiguously labelled according to its function.
Safety interlocks		
3	Coupling of safety interlock circuits	The control system must couple in series the facility interlock circuits with the radiation producing circuits so that radiation cannot be produced until the interlock system has been completely armed.
4	Panels and shields	All inspection panels and all removable shields must be interlocked. When an interlock is tripped, operation must resume only after manually resetting the interlock at the location where the interlock was tripped.
5	Electrical hazards	Interlocks must be provided to protect personnel from electrical hazards.
6	Sequentially interlocked controls	Sequentially interlocked controls must be provided for personnel access, irradiation room lockup sequence, and source energising or exposing operations. The controls must be designed such that any attempt to pre-empt or apply the controls out of sequence will automatically abort the intended operation.

Test	Compliance Test	Criteria for Passing the Test
Radiofrequency fields		
7	Radiofrequency fields	Radiofrequency exposure levels in accessible areas must comply with the requirements of Australian Standard AS2772.1-1990 *Maximum exposure levels – 100kHz to 300GHz*.[1]
Radiation level		
8	Outside accessible surfaces of machine sources	The radiation level measured at 30 centimetres from any accessible surface of the machine source must not exceed: (a) an average of 25μGy in one hour over any 100 centimetre square area; and (b) 25μGy in one hour over a one metre square area.
Single multipurpose key		
9	Single multipurpose key	A single multipurpose key must be provided to operate the irradiator during normal use. This key is used to operate the control console, to gain access to the radiation room, and to actuate the safety delay timer. The key must be attached to a portable radiation survey meter or audible warning device by chain or cable long enough to allow easy operation of all key switches. When the irradiator is fully operational, it must not be possible to remove the single multipurpose key without aborting irradiator operation.
Emergency stop device		
10	Emergency stop device on control console	An emergency stop device must be provided at the control console to prevent, quickly interrupt, or abort irradiator operations and return the radiation source to the de-energized condition at any time. This emergency stop device must be conspicuous, clearly labelled and provided in addition to any other means normally provided at the control console to shut down the irradiator.
Product entry and exit ports		
11	Product entry and exit port interlocks	Physical means must be provided on product entry and exit ports to prevent inadvertent or accidental entry of personnel into the irradiation room.

[1] The standard is available from Standards Australia, 232 St Pauls Terrace, Fortitude Valley, Brisbane.

Test	Compliance Test	Criteria for Passing the Test
12	Sources return to shielded position	If the entry or exit port control mechanism malfunctions the radiation source must return automatically to the de-energised condition.
Machine source operation		
13	Machine source operation	If a malfunction occurs with the machine source operation, the radiation source must return automatically to the de-energised condition and the irradiator must shut down.
Warning signs and alarms		
14	Audible or visible alarm	An audible or visible alarm must be provided to indicate that the entry or exit port control mechanism has malfunctioned.
15	Warning sign – entry and exit ports	Each product entry and exit port must be posted with appropriate warning signs.
16	Machine source operation	The machine source operation must be equipped with a device which positively indicates at the control console when the source is in the de-energised condition.
17	Machine source status indicators	Machine source status indicators must be provided at the control console to indicate: • When the machine source is fully shut down • When the machine source is fully energised.
18	Warning signs - panels, shields and interlocks	All inspection panels, removable shields, and interlocks must be posted with appropriate warning signs advising of their intended function, where this is pertinent, and of the hazards which might occur if they are removed.
Source guard		
19	Machine source guard	The machine source irradiator must be provided with adequate mechanical protection to prevent interference from items such as product boxes or carriers. For example, this may take the form of a protective shroud, guide bars, or floor guides on the product positioning system. Product positioning systems must not be able to apply force directly or indirectly to the machine source.

Test	Compliance Test	Criteria for Passing the Test
Product positioning system		
20	Product positioning system	The product positioning system must be provided with controls that detect a malfunction of that system, and which must cause the machine source to return automatically to the de-energised condition and the irradiator to shut down in the event of a malfunction.

Appendix A

Documents

National Health and Medical Research Council. *Code of Practice for the Design and Safe Operation of Non Medical Irradiation* Facilities (1988). NHMRC Publication No. 24, 1988.