Queensland Government

Radiation Safety Act 1999

RADIATION SAFETY STANDARD NM013:2010

Standard for sealed radioactive substances incorporated in sealed source apparatus used to carry out sterilisation

Preface

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

This radiation safety standard NM013:2010 *Standard for sealed radioactive substances incorporated in sealed source 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 sealed source 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 sealed source apparatus used to carry out sterilisation.

By ensuring compliance with this radiation safety standard, radiation protection around sealed source apparatus in Queensland will continue to be in accordance with the high standard for sealed source 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 NM013:2010 *Standard for sealed radioactive substances incorporated in sealed source apparatus used to carry out sterlisation*, for the purposes of the Act.

SIGNED

PAUL LUCAS MP
Deputy Premier
Minister for Health

19 / 08 / 2010

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Standard for sealed radioactive substances incorporated in sealed source apparatus used to carry out sterilisation

Section 1 – General

1.1 Scope

This radiation safety standard sets out the minimum requirements for sealed source 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.

“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.

"sealed source irradiator" means an irradiator in which the sealed radioactive substance is contained in a storage pool (usually containing water), and the sealed radioactive substance is fully shielded when not in use; the sealed radioactive substance is exposed within an irradiation room which is maintained inaccessible during use by interlocked controls.

Section 2 – Standard - Sealed source irradiator

Test	Compliance Test	Criteria for Passing the Test
Radioactive substance details		
1	Radioactive substance certification	The sealing of the radioactive substance must have: (a) a minimum sealed source classification system of ISO/C53424 or E53424, as specified in ISO2919-1980(E) *Sealed Radioactive Sources – Classification*[1], or equivalent; and (b) a minimum bend test classification of 5, as specified in Appendix A.
Interlocked controls		
2	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.
Single multipurpose key		
3	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 irradiation 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		
4	Emergency stop device on control console	An emergency stop device be provided at the control console to prevent, quickly interrupt, or abort irradiator operations and return the radiation source to the fully shielded or de-energised 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.

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

Test	Compliance Test	Criteria for Passing the Test
Product entry and exit ports		
5	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 high radiation areas.
6	Sources return to shielded position	If the entry or exit port control mechanism malfunctions the source must return automatically to the fully shielded condition.
7	Radiation monitor	Fixed radiation monitors with audible alarms must be located so that they detect radiation emitted through the product exit port. This monitoring system must be interlocked with the irradiator controls so that if radiation at the exit port exceeds a predetermined level, the conveyor which carries product from the radiation room to the exit port must stop and the radioactive substances must return automatically to the fully shielded position.
Radioactive substance exposure system		
8	Source operation	If a malfunction occurs in the source operation, the radiation substances must return automatically to the fully shielded condition and the irradiator must shut down.
Warning signs and alarms		
9	Audible or visible alarm	An audible or visible alarm must be provided to indicate that the entry or exit port control mechanism has malfunctioned.
10	Warning sign	Each product entry and exit port must be posted with appropriate warning signs.
11	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.
12	Source operation	The source exposure system must be equipped with a device which positively indicates at the control console when the radioactive substance is in the fully shielded condition.
13	Warning signal	A warning signal, which is audible both inside the irradiation room and at all access ports, must be provided to indicate when the radioactive substance is not fully shielded or in source-in-use status.

Test	Compliance Test	Criteria for Passing the Test
14	Source status indicators – control console	Source status indicators must be provided at the control console to indicate: (a) when the radiation source is fully shielded; and (b) when the radiation source is not fully shielded nor in the source-in-use status; and (c) when the radiation source is in the source-in-use status.
Source holder		
15	Source holder	It must not be possible to position and retain the sealed radioactive substance in the irradiation position.
Source guard		
16	Radiation source guard	The radiation source 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 radiation source.
Product positioning system		
17	Product positioning system	The product positioning system must be provided with controls that detect a malfunction of that system, and which must cause the radiation source to return automatically to the fully shielded or de-energised condition and the irradiator to shut down in the event of a malfunction.
Exposure prevention during servicing		
18	Disconnection of the motive power	A mechanism must be provided to disconnect the motive power used to expose the source, so that servicing can be carried out without the danger of the source being inadvertently exposed. It must be possible to positively secure this mechanism in the disconnected position.

Appendix A

Bend Test Classification Requirements

Bend test classification requirements

Sealed radioactive substances used in sealed source irradiators must have a minimum bend test classification of 5 based on the bend test procedures shown below.

Compliance with the test is determined by the ability of the sealed radioactive substances to maintain its integrity after the test is performed.

A radioactive substance complies with the bent test if the radioactive substance, due to its flexibility, passes through the test rig while under test (the centre of the force cylinder passes through the centreline of the two support cylinders) and maintains its integrity.

Sealed radioactive substance bent test

Bend tests apply for all radioactive substances having an L/D of 15 or more, where:

L = active length

D = minimum outer capsule diameter of the active length or the smallest cross-sectional dimension of non-circular sources.

A bend test classification of 5 is based on an applied static force of 2000 newtons (204 kilograms, using the following test parameters:

(a) all three cylinders must not rotate and must have longitudinal axes that are parallel to each other;

(b) the cylinders must have smooth surfaces and must be of sufficient length to accommodate the full contact surface of the capsule during the test procedures; and

(c) all cylinders are to be of a solid nature. Cylinder hardness should be ROCKWELL "C" 50-55.

In applying the static force, care should be taken not to apply this force suddenly as this will increase the effective force. The static force must be applied at the most vulnerable part of the sealed radioactive substance.

Appendix B

Documents

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