

Radiation Protection Act 2005 – Section 17

**CERTIFICATE OF COMPLIANCE:
STANDARD FOR RADIATION APPARATUS -
X-RAY INDUSTRY OR RESEARCH
(ENCLOSED SPECIAL)**

SECTION 1: REQUIREMENTS FOR CERTIFICATES OF COMPLIANCE.

SECTION 2: PARTS OF STANDARDS AND CODES OF PRACTICE ADOPTED BY THIS STANDARD.

This information can also be accessed at
http://www.dhhs.tas.gov.au/peh/radiation_protection

Section 1 – REQUIREMENTS FOR CERTIFICATES OF COMPLIANCE FOR CLASSES OF RADIATION APPARATUS.

This Standard is to be used when assessing Radiation Apparatus, classified by Radiation Protection Act 2005 licences as “X-ray enclosed special”, for the purpose of issuing a certificate of compliance.

In order for a certificate of compliance to be issued the Radiation Apparatus must be shown to fully comply with the requirements in Section 2.

† Where an item was demonstrated to comply at the time of manufacture or supply, ongoing compliance for that item may be stated only if it is reasonable to assume there has been no change, modification, damage or unacceptable wear and tear to that item since the time of manufacture.

The requirements in Section 2 are taken from the following.

NHMRC Statement

National Health and Medical Research Council
“Statement on enclosed X-ray equipment
for special applications (1987)”

Section 2 – PARTS OF STANDARDS AND CODES OF PRACTICE ADOPTED BY THIS STANDARD.

ITEM	Requirements
Labels and markings:	<p>A clearly visible sign bearing an ionizing radiation warning symbol (trefoil) and the word 'CAUTION' must be fixed to the equipment near the control panel, but it must be fixed to the part of the equipment containing the X-ray tube if this is separate from the control panel.</p> <p>In addition, the following or similar wording must be included on the sign: X-RAY EQUIPMENT This Unit produces radiation when energised. Access by unauthorised user and maintenance personnel prohibited.</p> <p>The lettering and symbol must be black on a yellow background. The statutory authority (see Annex) should be consulted with respect to this requirement.</p> <p>NHMRC Statement 11</p>
Indicators: energised X-ray tube	<p>The equipment must be fitted with an illuminated sign or combination of a sign and light, which displays the words 'X-RAYS ON' or wording of similar meaning and must be activated only when the X-ray tube is energised.</p> <p>The words must be legible and readily discernible for at least two metres on all accessible sides of the equipment. The sign or light specified in this statement must be designed to be 'fail safe' (i.e. to de-energise the X-ray tube if the light fails).</p> <p>Alternatively, adequate warning that a light has failed must be indicated in a clear and unambiguous manner.</p> <p>Where that part of the equipment containing the X-ray tube is separate from the main control unit, the sign or combination of sign and light referred to in the preceding paragraph must be fitted to the part containing the tube.</p> <p>An additional sign or combination of sign and light must be fitted to the main control and any other remote control but these do not require to be discernible on all accessible sides of the control.</p> <p>NHMRC Statement 10</p>
Definition of Controls:	<p>Controls referred to in the 3 requirements below are those which initiate and terminate the generation of X-rays, other than by the functioning of a safety interlock or mains power control.</p> <p>NHMRC Statement 6</p>
Keyed mains control	<p>There must be a key operated mains control so connected that X-rays cannot be produced when the key is removed.</p> <p>NHMRC Statement 6</p>
Separate exposure control	<p>There must be a separate switch for the control of the X-ray beam. Additional switches may be provided for remote operation.</p> <p>NHMRC Statement 6</p>
No automatic activation	<p>Where the X-ray tube is de-energised by the operation of a safety interlock, it must not automatically be re-energised by restoration of the interlock but must require the operation of a control switch.</p> <p>NHMRC Statement 6</p>
Unintentional exposure[†]	<p>An accidental earthing of an electrical conductor must not result in the production of X-rays.</p> <p>NHMRC Statement 7</p>

Safety interlocks	<p>A safety interlock is a device intended to prevent exposure of any part of the body to the primary X-ray beam or to intense scattered radiation by de-energising the X-ray tube under either of the following conditions:</p> <p>(a) when a door or access panel is opened; or (b) when two components or pieces of equipment interconnected by electrical or mechanical means are separated.</p> <p>Any safety interlock fitted in accordance with this statement must be so designed that it is difficult to render it ineffective or to operate it except by means of the appropriate door, panel or component.</p> <p>NHMRC Statement 4</p>
Access via entry port	<p>Where entry ports are provided for insertion of items or materials to be examined, the equipment must be so designed that insertion of any part of the body into the primary beam or into an intense beam of scattered radiation is not possible.</p> <p>Any panel or door which could permit access to the X-ray tube housing or any enclosure attached to it must be provided with at least one safety interlock and must comply with at least one of the following:</p> <p>(a) it must require the use of tools to open it; or (b) it must require the use of a key to open it and this must not be the same key required in statement 6 of the statement.</p> <p>NHMRC Statement 5</p>
Access for maintenance	<p>Where access to components associated with or adjacent to the tube housing and enclosures is required for maintenance purposes when the X-ray tube is energised, a key operated switch can be provided for exclusive use by authorised maintenance personnel to inactivate specified interlocks fitted to doors and access panels. This switch must not inactivate any interlock referred to in statement 8 of the NHMRC statement (see below). The key required for this switch must not be the same key as any other key required in the statement. This key operated switch must not permit access to the primary X-ray beam or to an area of intense scattered radiation.</p> <p>NHMRC Statement 5</p>

Radiation protection:	
Tube Housing	<p>An X-ray tube incorporated in an X-ray equipment to which this statement applies must be enclosed in a tube housing which satisfies the following requirements:</p> <p>(a) It must be constructed of material of sufficient strength and thickness to ensure that it cannot be fractured or deformed by normal use, accidental impact or misuse.</p> <p>(b) The radiation level at any accessible point 5 centimetres from the surface of the tube housing and any enclosure attached to it must not exceed 25 microgray in one hour when the X-ray tube is operated at any of the permissible ratings specified by the manufacturer of the equipment. Where any part of the tube housing and any enclosure attached to it form part of the external surface of the equipment, then the requirement of statement 3 must prevail.</p> <p>(c) Each aperture in the tube housing must be covered by:</p> <ul style="list-style-type: none"> • a radiation shield; • a completely shielded enclosure, any entrances to which are provided with safety interlocks, so that opening one entrance immediately de-energises the tube; or • a shielded enclosure within which there are permanently fixed baffles, shields or tunnels such that the external radiation level at any port which allows access to the enclosure is in compliance with statement 3 of the NHMRC statement. <p>(d) Each enclosure or radiation shield specified in clause 8(c) must comply with at least one of the following:</p> <ul style="list-style-type: none"> • it must be interlocked with the tube housing so that the detachment of the enclosure or shield from the housing de-energises the X-ray tube; or • it must be attached to the tube housing so that it can only be removed using tools and it must be provided with a warning label with the following or similar wording: DANGER High radiation levels inside. DO NOT remove when X-ray tube is energised. <p>(e) † The X-ray tube and tube housing must be interlocked so that removal of one from the other or the removal of protective covers from any aperture or service opening will immediately de-energise the tube.</p> <p>(f) † A safety interlock which uses a microswitch, fitted in accordance with this statement, must incorporate dual microswitches. Any other type of device used in a safety interlock must be of high reliability and comply with the appropriate Australian Standard.</p> <p>NHMRC Statement 8</p>
Filtration	<p>Where practicable, permanent filtration must be fixed in the X-ray beam to reduce the intensity of the beam to the minimum consistent with the proper operation of the equipment for its intended purpose.</p> <p>Permanent filtration must only be removable using tools. Where the equipment is intended for purposes which may require this filtration to be changed periodically, interlocks must be provided so that the X-ray tube cannot be energised unless filtration appropriate to the selected operating conditions is in place.</p> <p>NHMRC Statement 9</p>

radiation leakage of X-ray tube assemblies	<p>The radiation level at any accessible point 5 centimetres from the external surface of the equipment must not exceed 5 microsievert in one hour when averaged over an area of 100 square centimetres. Compliance with this requirement must be determined with the X-ray tube operated at any of the permissible ratings specified by the manufacturer of the equipment.</p> <p>NHMRC Statement 3</p>
Protection by shields ¹	<p>Radiation shields installed to achieve compliance with the external radiation limits in statement 3 must be made of lead attached to supporting material having substantially greater resistance to distortion than lead, or of other dense material with appropriate X-ray attenuation properties such as steel, brass or lead glass.</p> <p>NHMRC Statement 2</p>

¹ Reduction of radiation emitted through a port to the level permitted in this statement may be achieved by the use of baffles, tunnels providing distance protection or other equivalent method.