

Radiation Protection Act 2005

Guide for Suppliers Licensed to Sell, Service, Repair and Install Radiation Apparatus in Tasmania

This guide contains:

- A **checklist outlining the steps involved when selling** a radiation apparatus in Tasmania. Following the checklist will assist suppliers to comply with the legislation and their licence conditions.
- An **example certificate of compliance**. A licensed supplier is authorised by the *Radiation Protection Act 2005* to issue certificates of compliance for new radiation apparatus. All radiation apparatus in Tasmania must have a current certificate of compliance in order for them to be authorised for use.
- An **extract of the “sell” licence conditions**. This extract is provided to draw attention to the specific requirements relating to “sell”; however the full licence document and conditions must be complied with.

For assistance please phone:

Radiation Protection Unit: (03) 6222 7256

Email: radiation.protection@dhhs.tas.gov.au

Radiation Apparatus Identification Numbers (RAINs) may be requested by phone or email

Templates and Standards may be found at:

Web: www.dhhs.tas.gov.au/peh/radiation_protection

Checklist for a supplier licensed to “Sell, Service, Repair and Install” radiation apparatus in Tasmania (x-ray units, lasers - class 3B and class 4, MRI)

Step	Explanation	Outcome
<p>1 - The supplier must verify that the Tasmanian customer has a licence to possess the radiation apparatus.</p>	<p>The supplier’s licence conditions prohibit sale to unauthorised persons.</p> <p>Note: it is most likely that the customer will need to seek an amendment to their existing licence to authorise the acquisition of the new radiation apparatus.</p>	<p>Yes - The customer provided a 6 digit Tasmanian licence number of the form L/123456 with an expiry date of 31 August 20YY. Proceed to step 2.</p> <p>No - The supplier should advise the customer to contact the Radiation Protection Unit to arrange the necessary licence or amendment to licence. (03) 6222 7256 radiation.protection@dhhs.tas.gov.au</p> <p>Supplier must wait until the customer has their licence or licence amendment approved before proceeding to step 2.</p>
<p>2 - The supplier must check that the particular radiation apparatus type is authorised on the supplier’s licence.</p>	<p>The supplier’s licence can authorise many radiation apparatus (by type). Any model not listed on the supplier’s licence is currently not authorised for sale.</p>	<p>Yes - The supplier has verified that this make and model of radiation apparatus is authorised on the supplier’s licence. Proceed to step 3.</p> <p>No - The supplier needs to seek an amendment to their licence to sell this particular radiation apparatus type.</p> <p>The supplier must wait until the supplier’s licence amendment is approved before proceeding to step 3.</p>

Step	Explanation	Outcome
<p>3 - The supplier must check that the person(s) who will be installing the radiation apparatus is -</p> <p>EITHER authorised on the supplier's licence to service repair and install this type of radiation apparatus</p> <p>OR holds an individual licence in Tasmania which allows them to service, repair and install this type of radiation apparatus.</p>	<p>The supplier's licence can authorise many people under the single licence document. If changes in staff have occurred it may be that some staff are not currently authorised on the supplier's licence.</p>	<p>Yes - The supplier has verified that the person(s) who will install the radiation apparatus is either authorised on the supplier's licence or holds an individual licence. Proceed to step 4.</p> <p>No - The supplier needs to seek an amendment to their licence to include this person(s) as being authorised to "sell, service repair or install" (as the case may be), on the supplier's licence, or the person applies for an individual licence.</p> <p>The supplier must not permit any person to install the radiation apparatus until the supplier's licence amendment is approved.</p>
<p>4 - The authorised person, on behalf of the supplier, installs the radiation apparatus and certifies it under Tasmanian legislation.</p>	<p>The <i>Radiation Protection Act 2005</i> provides for a licensed supplier to issue the first certificate of compliance for a new radiation apparatus.</p> <p>The licensed supplier can do this if they have information that the radiation apparatus type complies with the Tasmanian Standard.</p> <p>The Radiation Apparatus Identification Number (RAIN) is basically a Tasmanian registration number for the radiation apparatus. It needs to be obtained from the Radiation Protection Unit and is required for completing the certificate of compliance.</p>	<p>Prepare and issue a: "CERTIFICATE OF COMPLIANCE: STANDARD FOR RADIATION APPARATUS – (particular type named here)". Compliance standards are based on the international and national Standards.</p> <p>Give the certificate to the Tasmanian customer and submit a copy to the Radiation Protection Unit.</p> <p>See over page for an example certificate of compliance.</p>

Example of a Certificate of Compliance for Fixed Medical Radiography Units

The *Radiation Protection Act 2005* provides for a licensed supplier to issue the first certificate of compliance for a new radiation apparatus. The licensed supplier can do this if they have information that the radiation apparatus type complies with the Tasmanian Standard. The Standards are available at:

http://www.dhhs.tas.gov.au/peh/radiation_protection/publications/standards_for_certificates_of_compliance

Tasmanian Radiation Protection Act 2005 Section 17(1)(b)

Certificate of Compliance: Radiation Apparatus

Issued by **<INSERT SUPPLIER COMPANY NAME>** as a company licensed in Tasmania to sell **<INSERT NAME of MANUFACTURER/ PARENT COMPANY>** radiation apparatus.

The Serial Number: **<INSERT MAKE and MODEL>**
Supplied to: **<INSERT SERIAL NUMBER>**
On: **<INSERT NAME of LICENCE HOLDER>**
Complies with the: **<DD/MM/YYYY>**
CERTIFICATE OF COMPLIANCE: STANDARD FOR RADIATION APPARATUS - X-RAY MEDICAL DIAGNOSTIC (FIXED ADIOGRAPHY)

<INSERT NAME OF MANUFACTURER/PARENT COMPANY> provided declaration of conformity documents which reference the following standards, or their IEC equivalent, to which conformity for this device is declared:

AS 3200.1.0-1998

AS/NZS 3200.1.3:1996

AS/NZS 3200.2.7:1999

AS/NZS 3200.2.28:1994

**RAR Regulatory Authority Requirement –
Department of Health and Human Services**

These standards are those required for a certificate of compliance for this type of apparatus, issued under the *Tasmanian Radiation Protection Act 2005*.

Certificate of Compliance number:

20YY - ____ - ____ - ____

To complete the certificate of compliance a Radiation Apparatus Identification Number (RAIN) for this particular apparatus needs to be obtained from the Radiation Protection Unit. Format of compliance number is YYYY-MM-DD-RAIN

Expiry date for certificate of compliance (date issued plus 2 years¹)

____/____/____

Signed _____ for **< INSERT SUPPLIER COMPANY NAME >**

Date ____/____/____

¹ The term of a certificate of compliance for most types of medical X-ray equipment is 2 years. Mammography is 1 year and bone mineral densitometers are 4 years. For other types of radiation apparatus please refer to Regulation 6 of the *Radiation Protection Regulations 2006*.

Extract of licence condition for SELL

Please consult with the supplier's licence documents to ensure full compliance.

Sell (as a supplier) radiation apparatus

Fit for purpose

The licence holder is authorised to sell the radiation apparatus listed in Schedule I (*of the seller's licence*) only for the purposes for which they have been specifically designed.

Compliance with relevant requirements

Any area of non-compliance with the relevant "Certificate of compliance: standard for radiation apparatus" that is identified and attributed to the time of manufacture must be rectified by the holder of this licence.

Note: *When a person who is licensed to sell a radiation apparatus is issuing a certificate of compliance, that person must be satisfied that the apparatus complies with all applicable codes of practice and any prescribed specifications.*

Provision of a full support service for the radiation apparatus

The licence holder may only sell the radiation apparatus listed in Schedule I (*of the seller's licence*) if they are in a position to provide or arrange a full support service (e.g. installation, servicing, repair, advice, training and documentation).

Prohibition of "sell" to unauthorised persons

A person authorised to sell (which includes to supply) a radiation apparatus is prohibited from selling or supplying to any person who does not hold a current licence to acquire and possess the particular radiation apparatus.

Note: *This includes the supply for the purposes of demonstration, trialling and/or evaluation, no matter how short the time period for this process.*