

*Radiation Protection Act 2005 – Section 17*

**CERTIFICATE OF COMPLIANCE:  
STANDARD FOR SEALED RADIATION SOURCE -  
GAMMA IRRADIATOR**

SECTION 1: REQUIREMENTS FOR CERTIFICATES OF COMPLIANCE FOR CLASSES OF RADIATION SOURCES

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](http://www.dhhs.tas.gov.au/peh/radiation_protection)

## **Section I – REQUIREMENTS FOR CERTIFICATES OF COMPLIANCE FOR CLASSES OF RADIATION SOURCES.**

**This Standard is to be used when assessing Radiation Sources, classified by Radiation Protection Act 2005 licences as “Sealed Irradiator”, for the purpose of issuing a certificate of compliance.**

**Note: This standard only applies to “dry source storage” irradiators.**

**In order for a certificate of compliance to be issued the Radiation Source 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 based on the following:**

**ANSI**

**American National Standard N433.1 “Safe design and use of self-contained, dry source storage gamma irradiators (Category I)”**

**RAR**

**Regulatory Authority Requirements**

## Section 2 - PARTS OF STANDARDS AND CODES OF PRACTICE ADOPTED BY THIS STANDARD OF COMPLIANCE

| Item  | Requirements                   |
|---|--------------------------------|
| <b>Manufacturer's Responsibility</b>  | <i>ANSI 6.1<sup>†</sup></i>    |
|   | <i>ANSI 6.2<sup>†</sup></i>    |
|   | <i>ANSI 6.3<sup>†</sup></i>    |
|   | <i>ANSI 6.4<sup>†</sup></i>    |
| <b>Maximum Permissible Radiation Levels – Measurement Configuration<sup>†</sup></b> | <i>ANSI 7.2</i>                |
| <b>“Source in Use” – “Source not in Use” Exposure level</b>                         | <i>ANSI 7.3.1</i>              |
| <b>During sample loading and unloading</b>  | <i>ANSI 7.3.1.1</i>            |
| <b>Temporary Sample Load/Unload Condition Exposure level</b>                        | <i>ANSI 7.3.2</i>              |
| <b>Transient Condition Exposure level</b>   | <i>ANSI 7.3.3</i>              |
| <b>Hand Operated Exposure level</b>   | <i>ANSI 7.3.3.1</i>            |
| <b>Survey by Manufacturer on New Irradiators</b>                                    | <i>ANSI 7.4.1<sup>†</sup></i>  |
| <b>Interlocks</b>   | <i>ANSI 8.2.1<sup>†</sup></i>  |
| <b>Movable Shielding</b>  | <i>ANSI 8.2.2<sup>†</sup></i>  |
| <b>Incorrect Procedure</b>  | <i>ANSI 8.2.3<sup>†</sup></i>  |
| <b>Power Failure</b>  | <i>ANSI 8.4<sup>†</sup></i>    |
| <b>Integrity of Shield</b>  | <i>ANSI 9.1<sup>†</sup></i>    |
| <b>Unencased Shield</b>   | <i>ANSI 9.1<sup>†</sup></i>    |
| <b>Encasement thickness</b>   | <i>ANSI 9.3<sup>†</sup></i>    |
| <b>Encasement penetration</b>   | <i>ANSI 9.4<sup>†</sup></i>    |
| <b>Tubes through encased shielding</b>  | <i>ANSI 9.5<sup>†</sup></i>    |
| <b>Source Holder</b>  | <i>ANSI 10.1.1<sup>†</sup></i> |
|   | <i>ANSI 10.1.2<sup>†</sup></i> |
|   | <i>ANSI 10.2<sup>†</sup></i>   |
| <b>Movable sources(s)</b>   | <i>ANSI 8.2.†</i>              |
| <b>Controls and Indicators</b>  | <i>ANSI 11.1</i>               |
| <b>Status indicator colours</b>   | <i>ANSI 11.2</i>               |
| <b>Status of the irradiator to be “Obvious”</b>                                     | <i>ANSI 11.3</i>               |
| <b>Master Control Required</b>  | <i>ANSI 11.4</i>               |
| <b>Termination of Use</b>   | <i>ANSI 11.5</i>               |
| <b>Labelling</b>  |                                |
| <b>Isotope, activity and date of measurement</b>                                    | <i>ANSI 12.1.1</i>             |
| <b>Caution or Danger Radioactive Material</b>                                       | <i>ANSI 12.1.1</i>             |

|                                |   |
|--------------------------------|---|
| <b>Maximum Source Capacity</b> | <b>ANSI 12.1.3</b>  |
| <b>Separate Control panel</b>  | <b>ANSI 12.1.4</b>  |
| <b>Securing of Labels</b>      | <b>ANSI 12.1.5</b>  |
| <b>Wipe Test <sup>1</sup></b>  | <b>ANSI 17.4.1</b>  |
| <b>Contamination Level</b>     | <b>ANSI 17.5.1</b><br>Non fixed contamination levels must not exceed those specified in ISO 9978.<br><b>RAR</b> |

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<sup>1</sup> **WIPE TEST** is based on taking with wet or dry tissue possible radioactive contamination from source surface. The tissue may be wetted with water, diluted nitric acid or another solution inactive for capsule material but actively removing radioactive contamination. If measured activity of tissue does not exceed 185 Bq (5 nCi) the source surface proves to be non-contaminated.