



# Certification Process for Prescribed Equipment



## Staff Presentation to Commission

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# Background

- 2019-2020: Event Initial Reports (EIRs) presented to the Commission related to Fixed gauges
- Commission asked questions on the design and regulatory requirements of these gauges
- 2021: CNSC staff provided their responses
- Commission was satisfied with the CNSC responses
- Today, CNSC staff is taking the opportunity to share information on the certification process of all Prescribed Equipment with the Commission



# Outline

- Definition of prescribed equipment
- Designated Officer duties and responsibilities
- Applicable regulations for certification of prescribed equipment
- Certification process for prescribed equipment
  - Radiation Devices
  - Class II Prescribed Equipment
  - Transport packages
- Summary





Certification Process for Prescribed Equipment

# Definition of Prescribed Equipment



# Prescribed Equipment

In accordance with Section 20 of the *General Nuclear Safety and Control Regulations*, prescribed equipment includes:

- Transport packages
- Radiation devices
- Class II prescribed equipment

## Prescribed Equipment

**20** Each of the following items is prescribed equipment for the purposes of the Act:

**(a)** a package, special form radioactive material, low dispersible radioactive material, fissile-excepted radioactive material, radioactive material that has a basic radionuclide value that is not listed in the IAEA Regulations and an instrument or article that has an alternative activity limit for an exempt consignment, as those terms are defined in subsection 1(1) of the *Packaging and Transport of Nuclear Substances Regulations, 2015*;

**(b)** a radiation device and a sealed source, as defined in section 1 of the *Nuclear Substances and Radiation Devices Regulations*;

**(c)** Class II prescribed equipment, as defined in section 1 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations*; and

**(d)** equipment that is capable of being used in the design, production, operation or maintenance of a nuclear weapon or nuclear explosive device.



# Prescribed Equipment that needs to be certified

The design of the following types of prescribed equipment need to be certified by the CNSC:

- Any radiation device containing more than an exemption quantity of nuclear substance
- All Class II prescribed equipment
- Transport packages designed to contain nuclear substances above the limits specified in the IAEA Regulations
- Radioactive sources that meet the testing requirements of IAEA Regulations

**Most prescribed equipment  
must be certified before use in Canada**



# Why certify Prescribed Equipment?

Certification of prescribed equipment confirms:

- The prescribed equipment is safe to use
- Adequate measures are in place to protect the environment, the health, safety and security of persons





Certification Process for Prescribed Equipment

Designated Officer  
duties and responsibilities





# Designated Officers

**Section 37** of the *Nuclear Safety and Control Act* allows the Commission to authorize a designated officer to certify and decertify prescribed equipment.

Three designated officers in the Transport Licensing and Strategic Support Division (TLSSD) in the Directorate of Nuclear Substances Regulation (DNSR)

In 2021, **70 certification decisions** were made in accordance with Section 37 (2)(a) (*certify and decertify prescribed equipment*)



# Designated Officer Decision Making

Independent and subject to rules governing procedural fairness and impartiality

Refusals to certify and decertification decisions allow for an opportunity to be heard by the Designated Officer



## Certification Process for Prescribed Equipment

Applicable regulations  
for certification of  
prescribed equipment





# Act and Regulations Related to the Certification of Prescribed Equipment

## ***Nuclear Safety and Control Act***

Section 44 (1) (q) authorizes the commission to make regulations for certification and decertification of prescribed equipment.

## ***Nuclear Substances and Radiation Devices Regulations***

Section 11 (1) provides certification requirements for a radiation device.

## ***Class II Nuclear Facilities and Prescribed Equipment Regulations***

Section 10 provides certification requirements for Class II prescribed equipment.

## ***Packaging and Transport of Nuclear Substances Regulations, 2015***

Section 10(1) provides requirements to certify design of prescribed equipment.



# Other Applicable Regulations for the Certification of Prescribed Equipment

## ***General Nuclear Safety and Control Regulations***

Section 20 defines prescribed equipment.

## ***Radiation Protection Regulations***

Section 12, 13 and 14 provide radiation dose limits.

Section 20 provides labelling requirements for radiation devices.

## ***Cost Recovery Fees Regulations***

Section 21 and Schedule 2 provide fixed cost recovery fee requirements for the certification of prescribed equipment.



# Overview of Certification Process for the Prescribed Equipment

- Application is reviewed against the regulatory requirements and any applicable standards
- An internal peer-review is done of the assessment to ensure quality assurance
- Recommendation is forwarded to the designated officer
- Designated officer does the final review and renders their decision
- Opportunity to be heard process exists in cases where certification is not granted

**Certification engineers are required to be qualified as professional engineers**





Certification Process for Prescribed Equipment

# Certification process for Radiation Devices



# Radiation Devices

## Radiation device is defined as:

- “A device that contains more than the exemption quantity of a nuclear substance and that enables the nuclear substance to be used for its radiation properties; and
- A device that contains a radium luminous compound”

There are ~500 radiation device designs certified in Canada

## Radiation devices include (but are not limited to):

Fixed gauges  
Portable gauges  
Exposure devices used for Industrial radiography  
X-ray fluorescence analysers  
Calibrators  
Radioluminescent devices



**Portable gauges**

Photo Source:  
Wikipedia Commons



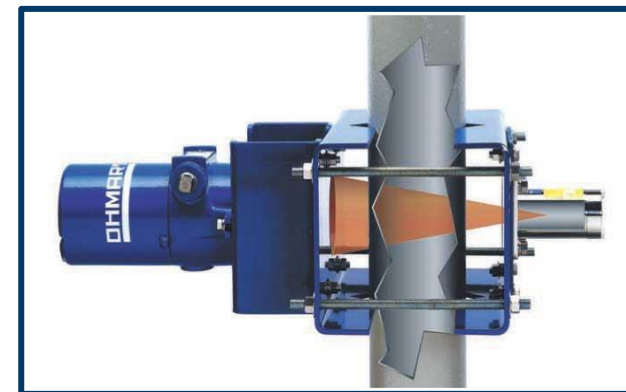
**SHLM CR fixed gauge**

Photo Source:  
Ohmart Vega



**Fixed nuclear gauge**

Photo Source:  
Endress + Hauser



**Fixed gauge mounted on a pipe**

Photo Source: Ohmart Vega



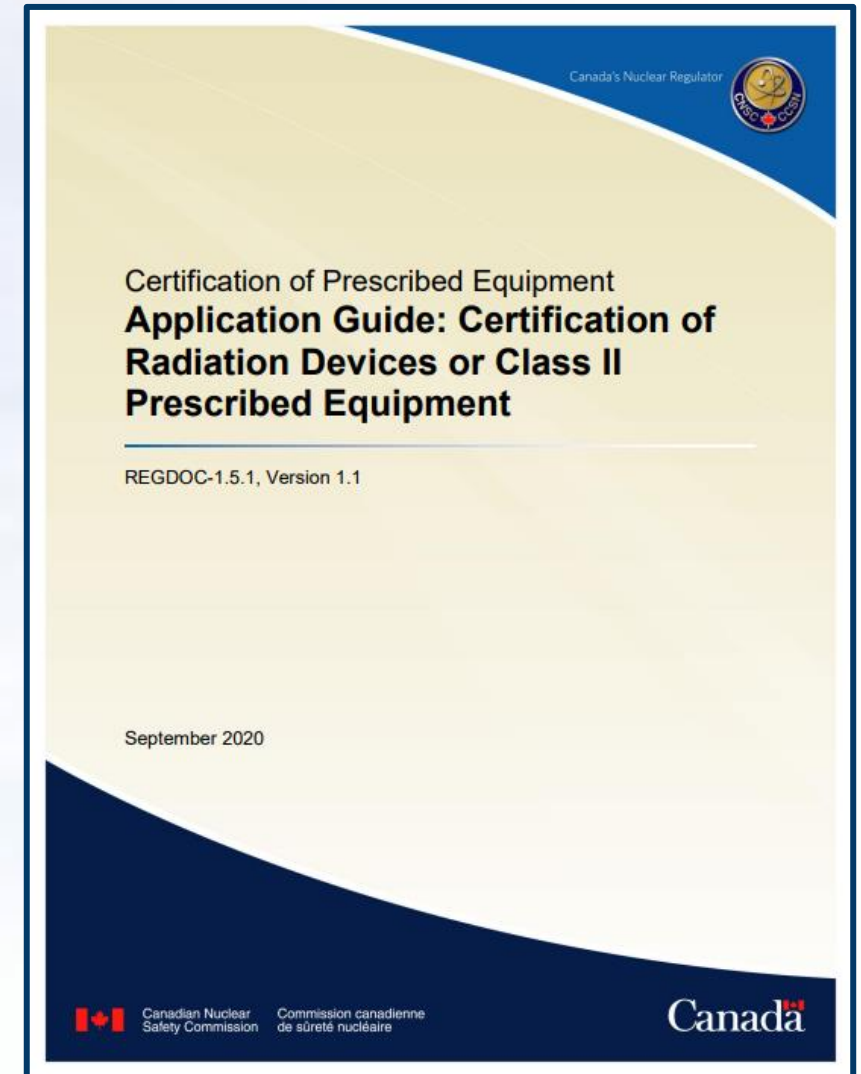


# Application Guide for Certification

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## **REGDOC-1.5.1** *Application Guide: Certification of Radiation Devices or Class II Prescribed Equipment*

Contains detailed information on the content of an application for certification of any radiation device or Class II prescribed equipment.





# Radiation Devices - Technical Assessment

Technical assessment for radiation devices is done for areas such as:

- Overall design, material properties, detailed drawings and quality assurance plan
- Shielding to ensure that the dose rate around the device is within the acceptable limits (ANSI/ISO standards and PTNSR, 2015)
- Source assembly design for its safe operation
- Recommended inspection and maintenance schedule by the manufacturer
- Emergency procedures as they relate to the operation of the device
- Documents provided for the safe operation of the device (e.g. user manual)



# Radiation Devices - Applicable Standards

- *ANSI N43.8 Classification of ionizing radiation gauging devices*
  - Performance and testing requirements
  - Temperature, radiation, fire accident conditions
- *ISO 7205 – Radionuclide gauges – Gauges designed for permanent installation*
- *ISO 3999 (ANSI N43.9) – Industrial gamma radiography (Exposure Devices) – Specifications for performance, design and tests*
- *ISO 2919 (ANSI N43.6) – Sealed radioactive sources – General requirements and classification*
  - Temperature, external pressure, impact, vibration, puncture, bending
- *ISO 9978 – Sealed sources leakage test methods*
- *IAEA RS-G-1.9: Categorization of radioactive sources*
- *IAEA Specific safety guide No. SSG-58 - Radiation safety in the use of nuclear gauges*

**Meeting standards is good industry practice**



## Industrial Radiography

Exposure devices are radiation devices used primarily for the examination of the integrity of the welds by the remote manipulation of large sources of a nuclear substance to expose photographic film.

Industrial radiography is a high-risk activity.

Workers in the industrial radiography industry had the highest average doses. This warranted additional requirements.

**REGDOC-2.5.7:** *Design, Testing and Performance of Exposure Devices* largely refers to ISO 3999



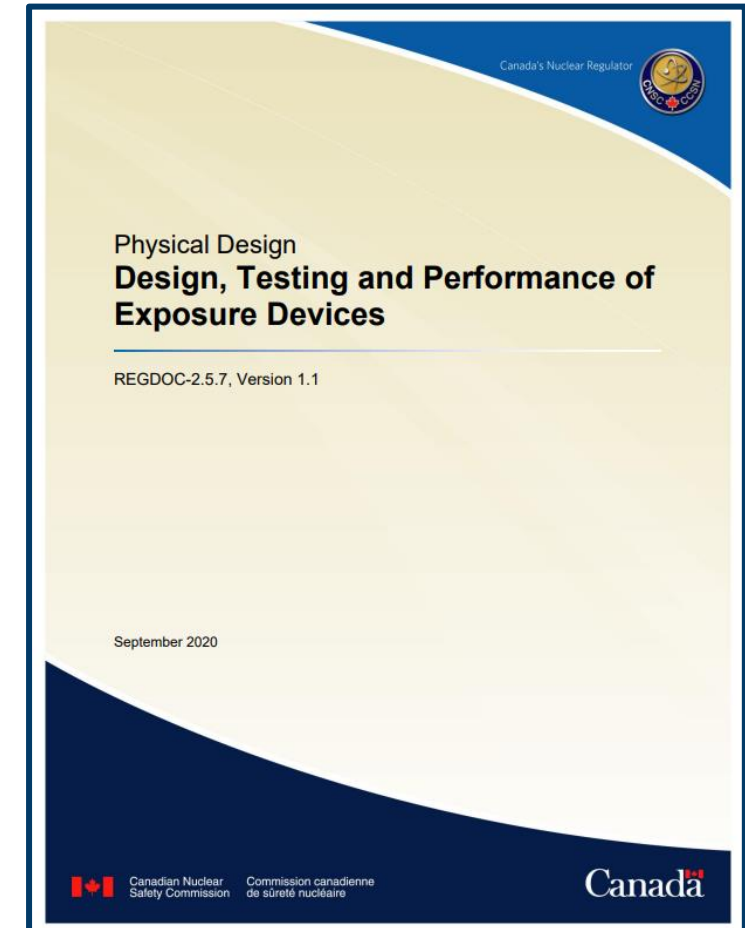
**Exposure device – pipeline crawler**

Photo source: Welding and NDT Institute



**Exposure device**

Photo source: SPEC





**Cable-operated exposure device**

Photo source: Welding and NDT Institute



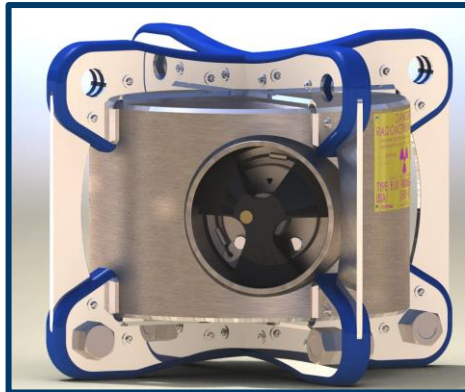
**Model TSI 3/1**

Photo Source:  
Nordion



**Model 1075 ScarPro**

Photo source: QSA Global



**Model Sentry 110**

Photo source: QSA Global



**Model 959**

Photo source: QSA Global



**Exposure device – pipeline crawler**

Photo Source: Welding and NDT Institute





Certification Process for Prescribed Equipment

Certification process for  
Class II Prescribed Equipment

## Examples of Class II prescribed equipment

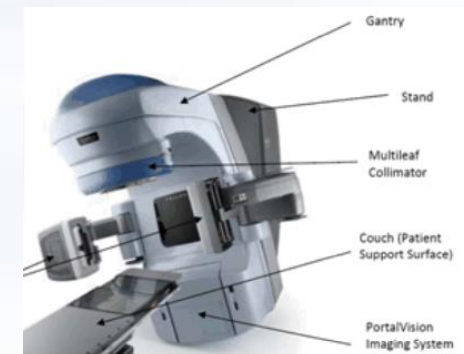
- **Irradiators** over certain limits or that require a shielding enclosure
- Radioactive source **teletherapy machines**
- **Particle accelerators** (includes linear accelerators and cyclotrons)
- **Brachytherapy remote afterloaders**

There are ~150 Class II Prescribed Equipment designs certified in Canada



**Teletherapy machine (Gamma knife)**

Photo source: Elekta



**Linear accelerator**

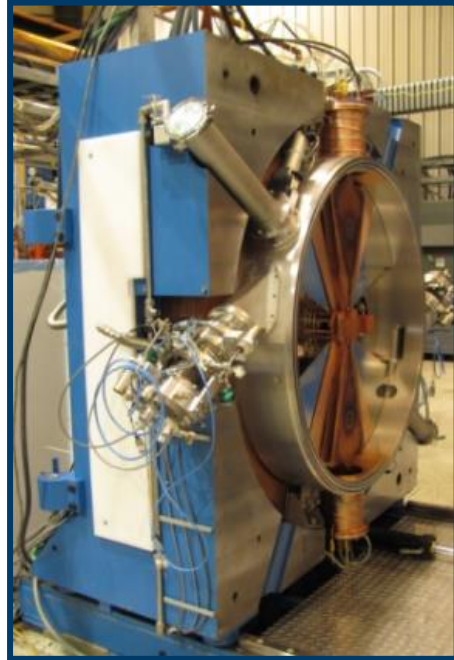
Photo source: Varian/CNSC



# Examples of Class II Equipment



**Research irradiator**  
Photo source: Hopewell



**Cyclotron**  
Photo source: CNSC



**Medical linear accelerator**  
Photo source: Elekta



**Remote afterloader  
brachytherapy**  
Photo source:  
Elekta



Photo source:  
Varian



# Class II Prescribed Equipment Technical Assessment

**Class II prescribed equipment technical assessment is done for areas such as:**

- Overall design, safety systems, materials, detailed drawings and tests performed
- Shielding, mechanical, thermal and electrical hazards
- Emergency control systems, backup power supply
- Recommended inspection and maintenance schedule by the manufacturer
- Emergency procedures and systems as they relate to the operation of the device
- Documents provided for the safe operation of the equipment
- Quality assurance plan



# Class II Prescribed Equipment - Applicable Standards

## ***CSA 60601-2-1: Requirements for the basic safety and essential performance of electron accelerators in the range of 1 MeV to 50 MeV***

Establishes requirements to be complied in the design and construction of electron accelerators used for treatment of patients.

## ***ANSI N43.1: Radiation safety for the design and operation of Particle Accelerators***

Sets forth design and other requirements for non-medical accelerators.

## ***ANSI N43.10: Safe design and use of gamma irradiators***

Establishes the criteria to be used in the proper design, fabrication, installation, use, and maintenance of these irradiators, which will ensure a high degree of radiation safety.





**Health Canada's medical devices directorate** is responsible for issuing licenses for medical devices - including some Class II prescribed equipment and accelerators used for medical purposes.

- Health Canada review primarily based on clinical evidence
- Covers safety of the equipment in all aspects, not just nuclear
- CNSC issues the certificate for medical devices only after a license is issued by Health Canada

**A Memorandum of Understanding (MOU)** between CNSC and Health Canada is in place.

MOU requires the CNSC and Health Canada to:

- Cooperate in investigations
- Share certificate assessment information



Certification Process for Prescribed Equipment

Certification process  
for transport packages

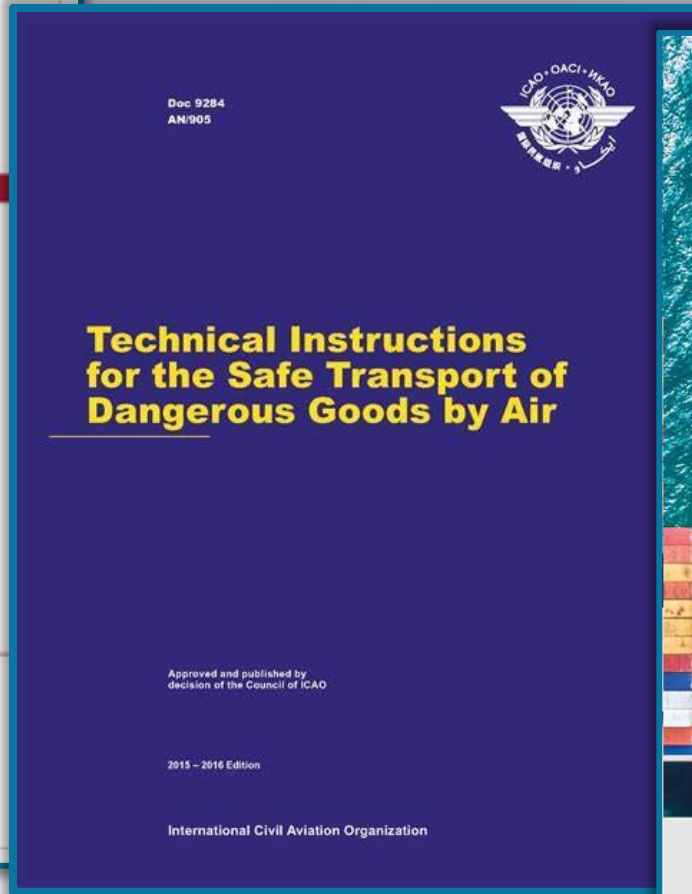
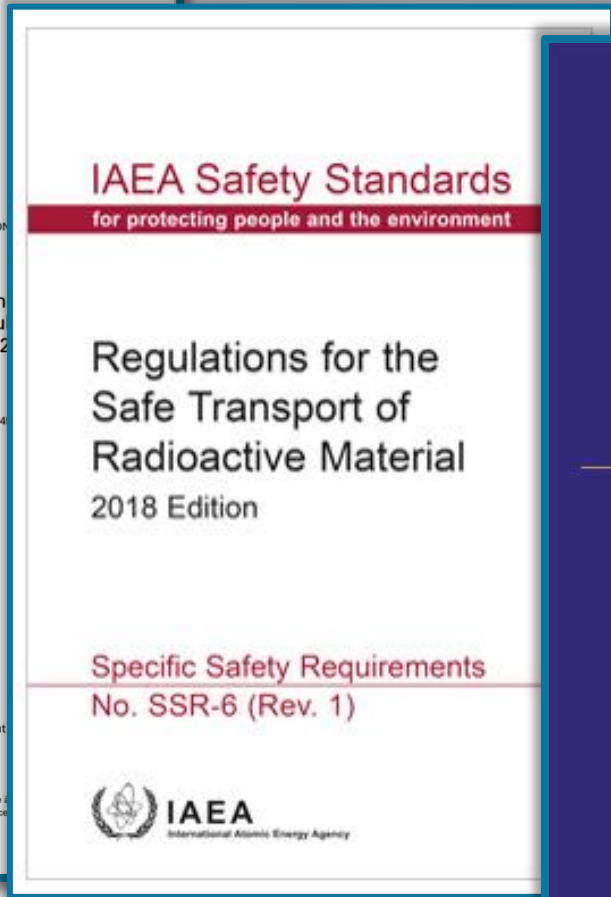
# Transport of Nuclear Substances

- United Nations regulations and Transport Canada regulations classify dangerous goods into nine classes - Class 7 is the one related to radioactive material
- Millions of shipments of different dangerous goods each year in Canada
- About 1 million shipments of radioactive material - less than 3% of the total
- Worldwide over 10 million radioactive material packages are safely transported each year by road, sea, rail or air



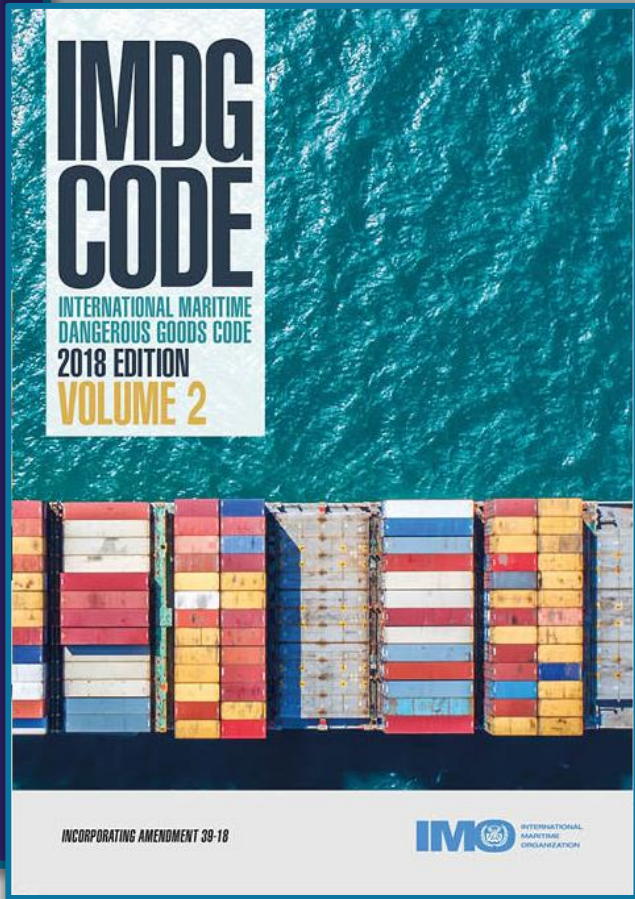
Transport of radioactive material is jointly regulated by the CNSC and Transport Canada. CNSC is responsible for the certification of packages.





By air

By sea



CNSC applies the IAEA regulations through ambulatory reference



# Transport Package Certification Requirements

Types of Packages that do not require CNSC certification	Packages requiring CNSC certification
<ul style="list-style-type: none"><li>• Excepted package</li><li>• Industrial type packages</li><li>• Type A package</li></ul>	<ul style="list-style-type: none"><li>• Type B package</li><li>• Type C package</li><li>• Type H package (uranium hexafluoride package)</li><li>• Fissile material packages</li></ul>

**There are ~75 certified transport package designs in Canada**

**All packages used for the transport of nuclear substances are subject to the regulations but only some packages require certification based on risk**



# Regulatory Test Requirements for Transport Packages

Not Certified

Certified

Requirements	Excepted Packages	Industrial Packages	Type A Packages	Type B & Fissile Packages	Type C Packages	Type H Packages
General requirements	X	X	X	X	X	X
Water Spray Tests		X	X	X	X	
Free Drop Tests		X	X	X	X	X
Stacking Test		X	X	X	X	
Penetration test		X	X	X	X	
Mechanical tests (multiple drop tests)				X	X	
Thermal test				X		X
Water Immersion Test				X		
Puncture/tearing tests					X	
Enhanced Thermal tests					X	
Enhanced Water Immersion Test					X	
Impact test					X	
Pressure Test						X

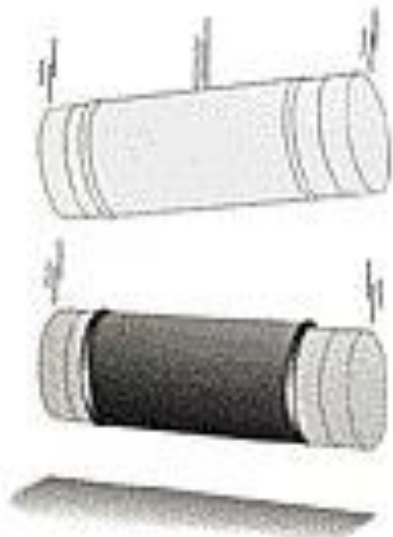
Package design and testing requirements are commensurate with the risk posed

Legend

Blue	Normal Conditions
Red	Accident Conditions

Type B Packages are designed to withstand a series of tests that simulate accident conditions of transport

Accident conditions of transport



Drops from 9 m heights (\*)



Drop from 1 m on a punch bar



Fire at 800°C, 30 mn



Immersion under 15 m

\* On an unyielding surface



# Examples of Transport Packages



**Type IP industrial package**  
Photo source: CNSC



**Type A package**  
Photo source: Nordion



**Type B package for medical isotopes**  
Photo source: Nordion



**Type H package for natural uranium hexafluoride**  
Photo source: CNSC



**Type B(F) package for nuclear fuel (fissile)**  
Photo source: NAC



**Type B package – radiography camera**  
Photo source: QSA Global

Greater the radioactivity, the more robust is the package design



# Transport Package Technical Assessment (1/2)

**To obtain CNSC certification, the applicant must submit information such as:**

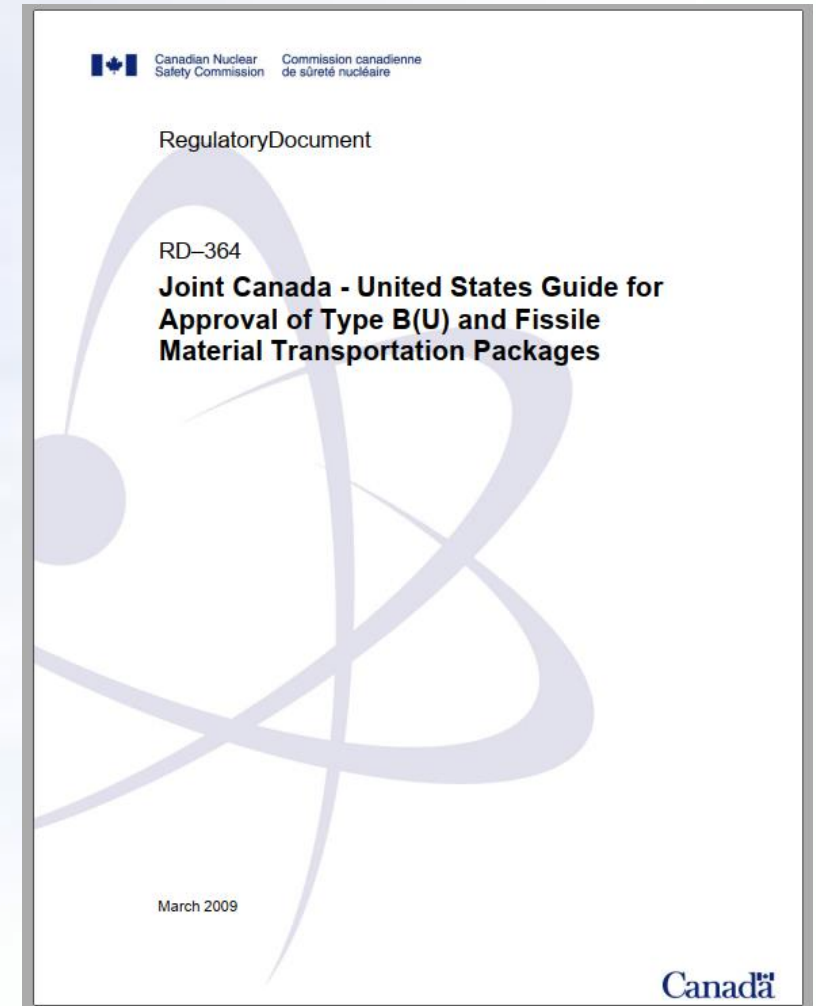
- The design of the package (structural, thermal, shielding, criticality, quality assurance program)
- Engineering drawings
- Test results
- The recommended inspection and servicing program
- Instructions for the maintenance and use of the package
- Any other information necessary to demonstrate that the design meets the applicable requirements of the regulations



# Transport Packages Technical Assessment (2/2)

Packages certified in other countries still have to be reviewed and approved by CNSC before they can be used in Canada.

**CNSC published RD-364:** Joint Canada-US guide that provides format and content for applications for approval of Type B(U) and fissile material transportation packages.





# Summary

- Design requirements for prescribed equipment are commensurate with the risk posed by them
- A rigorous review process is in place for certification of prescribed equipment
- CNSC follows widely accepted industry standards for certification of radiation devices and Class II prescribed equipment
- For packaging and transport, CNSC incorporates IAEA regulations by ambulatory reference
  - The 2019 IRRS mission noted that Canada has a robust regulatory framework for the packaging and transport of nuclear substances

**CNSC has a rigorous and robust process for certifying prescribed equipment**



*We will never compromise safety*  
*Nous ne compromettrons jamais la sûreté*



Canadian Nuclear  
Safety Commission

Commission canadienne  
de sûreté nucléaire