HEALTH CANADA

Program: Radiation Emitting Devices

LIVINGSTON
Simplify Trade

PGA: Health Canada

Program: Radiation Emitting Devices

The Canada Border Services Agency (CBSA) assists Health Canada with the administration of the Radiation Emitting Devices Act and regulations made thereunder.

The **Radiation Emitting Devices Act** sets the requirements for all devices that give off radiation, except those subject to the:

- **Motor Vehicle Safety Act**
- **Nuclear Safety and Control Act**

In Canada, all devices must comply with the standards outlined in the Radiation Emitting Devices Act if they will be:

- Sold
- Resold
- Leased
- Imported

Companies are required to comply with federal requirements concerning aspects such as:

- Labelling
- Emissions
- Construction
- Performance

Radiation-emitting devices classed as consumer products must meet additional requirements of the **Canada Consumer Product Safety Act.** Medical devices must meet the regulations in the **Food and Drugs Act.**

A Radiation Emitting Device is defined as any device that is capable of producing and emitting radiation, or any component of or accessory to a device that is capable of producing and emitting radiation.

Implementation of the CBSA Single Window Initiative (SWI)

Under the Single Window Initiative, release requests will be submitted utilizing a new Integrated Import Declaration (IID) that allows custom brokers to submit and obtain electronic release for goods also regulated by participating department and agencies.

Release requests for Radiation Emitting Devices may be provided to the CBSA electronically by submitting an IID.

Note: Under SWI, information requirements will remain the same. There are no additional data requirements for the import process.

Harmonized System (HS) Codes

List of HS codes applicable to goods that may be regulated by Health Canada for Radiation Emitting Devices:
https://www.cbsa-asfc.gc.ca/prog/sw-gu/regcom-marreg/codes-eng.html

Data Element Rationales

The following data element rationales provide additional information of the specific data element requirements required under the Single Window Initiative.

Importer Contact Name	PGAs to contact the importer for IID clarification.
Importer Contact Telephone Number	PGAs to contact the importer for IID clarification.

Importer Contact Email Address	PGAs to contact the importer for IID clarification.
LPCO Type	Importer must ensure that the product meets the appropriate licensing type to be imported.
LPCO Number	Importer must ensure that the product has a valid licensing number demonstrating its authorization for sale/use in Canada as applicable (DIN, No Objection Letter, etc.)
File	Optional
FDA Product Code	Optional
Model Designation	Necessary for identifying radiation emitting device class or product.
Commodity Type	The Canadian Product Category, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number required.
LPCO Type	Importer must ensure that the product meets the appropriate licensing type to be imported.
LPCO Number	Optional
File	Optional

Electronic Commerce Client Requirements Document (ECCRD)

The following table provides the specific rules and conditions associated to each of the data elements for HC Declarations. The data elements are: Mandatory (M), Conditional (C) or Optional (O).

Data element name	PGA element definition	Data element status	Data element rules and conditions
Contact Identification	Importer Contact Name	O	For Health Canada - Radiation Emitting Devices, it is recommended to provide a contact name for the Importer.
Contact Method	Importer Contact Telephone Number	O	For Health Canada - Radiation Emitting Devices, it is recommended to provide a contact telephone number for the Importer.
Contact Method	Importer Contact Email Address	O	For Health Canada - Radiation Emitting Devices, it is recommended to provide a contact e-mail address for the Importer.

Document Type (Licence, Permit, Certificate, Other)	LPCO Type	O	For Health Canada – Radiation Emitting Devices that are also medical devices, a license must be provided (see Appendix B6.8 Medical Devices). Otherwise, the provision of documents, licences, permits and/or other documents is optional. Providing this information may help to expedite communication in case of a referral. The coded identifier of applicable document types being provided at the declaration level must be provided in this field. Document types provided here must be applicable to all commodities on this declaration. If not applicable to all commodities, please provide the document types at the commodity line level (SG121). Acceptable documents types include: • Product Label
Document Reference Number	LPCO Number	O	For each document provided at the declaration level, the associated reference number related to that document should be provided. For document types which do not contain an LPCO number, provide the generic LPCO Number 'XXX'.
Document Source Description	File	O	For each document provided at the declaration level, it is strongly recommended to provide an image of the document can be accessed by qualified CBSA and Health Canada employees. Providing an image may facilitate communication in case of a referral.
Commodity Identifier (FDA Number)	FDA Product Code	O	Radiation Emitting Devices can be identified through their FDA Product Codes (United States Federal Drug Administration). Provision of this information allows clearer identification of the product and may facilitate communications in the case of referrals. The qualifier for FDA Product Code must be provided in the 7402, 2 field.
Commodity Description (Model Name)	Model Designation	M	Model designation of the commodity being imported must be provided.

Model designation of the commodity being imported must be provided.	Commodity Type	M	For Health Canada – Radiation Emitting Devices, the provision of a Canadian Product Category is mandatory. This information may allow a clearer identification of the product and may help to expedite communication in the case of a referral. One of the following Canadian Product Categories must be provided: • Tanning Equipment • X-ray Device • Ultrasound Therapy Device • Microwave Oven • Laser • Other The qualifier for field 5389 should be the code for HC – Radiation Emitting Device.
Document Type (Licence, Permit, Certificate, Other)	LPCO Type	O	For Health Canada – Radiation Emitting Devices that are also medical devices, a license must be provided (see Appendix B6.8 Medical Devices). Otherwise, the provision of documents, licences, permits and/or other documents is optional. Providing this information may help to expedite communication in case of a referral. The coded identifier of applicable document types should be provided in this field if applicable to a specific commodity line entry. If applicable to all commodities, please provide the document types at the declaration level (SG9). Acceptable documents types include: • Product Label
Document Reference Number	LPCO Number	O	For each document provided at the commodity level, the associated reference number related to that document must be provided. For document types which do not contain an LPCO number, provide the generic LPCO Number ‘XXX’.
Document Source Description	File	O	For each document provided at the commodity line level, it is strongly recommended to provide an image of the document that can be accessed by qualified CBSA and Health Canada employees. Providing an image may facilitate communication in case of a referral.

Additional resources

Regulated Commodities:

Reference Code Tables

Legislative References:

Radiation Emitting Devices Act

Radiation Emitting Devices Regulations

Custom Memoranda:

The Administration of Health Canada Acts and Regulations Relating to Certain Controlled, Prohibited or Regulated Goods. Memorandum D19-9-1

https://www.cbsa-asfc.gc.ca/publications/dm-md/d19/d19-9-1-eng.html

Contact Livingston

Have questions or need help with your SWI imports?
Contact your Livingston client services representative.
Write to us at: **clientserviceCanada@livingstonintl.com** or give us a call at **1-855-225-5544**.