Health Canada

Guidance on Advance Notice of Importation under section 21.1 of the *Medical Devices Regulations* (MDR) and section 3.1 of the *Radiation Emitting Devices Regulations* (REDR).

Disclaimer

This document does not constitute part of the *Food and Drugs Act* or the *Radiation Emitting Devices Act* (the Acts) or associated regulations. In the event of any inconsistency or conflict between this document and the Acts or regulations, the Acts or regulations take precedence. This document is administrative and intended to facilitate compliance with the Acts, regulations, and applicable policy by regulated parties.

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1.0 Purpose

This document provides guidance to regulated manufacturers and importers wishing to invoke section 21.1 of the *Medical Devices Regulations* (MDR) and section 3.1 of the *Radiation Emitting Devices Regulations* (REDR).

Medical devices, including those that are also radiation emitting devices, imported for the purposes of these sections are required to have non-compliant device labelling corrected prior to their sale in Canada as well as comply with all provisions of those regulations and the Acts applicable to their devices in order for their sale to be lawful in Canada.

This document also provides instructions for completing and submitting the Advance Notice of Importation (ANI) Form (Medical Devices). Health Canada (HC) will permit importers of medical devices to submit a single ANI Form for multiple medical devices. This notice will be valid for a maximum period of three months. Relabelling must occur within three months of the date of importation.

2.0 Background and Scope

Background

No person shall import or sell a medical device unless it meets the requirements of the MDR. In the case of a medical device that also falls within the definition of a radiation emitting device, no person shall import, sell or lease such a device unless it meets the requirements of the MDR and REDR. The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), ratified by Canada on October 29, 2018, resulted in amendments to section 21.1 of the MDR and section 3.1 of the REDR allowing for the importation of medical devices with non-compliant labelling, provided that labelling corrections are performed within three months of the date of their importation and prior to their sale in Canada.

Scope

This document pertains to the importation of medical devices that will be relabelled, which can include supplemental labelling, prior to being sold in Canada as per section 21.1 of the MDR and section 3.1 of the REDR, as the case may be, to help enable their sale to be lawful in Canada under the FDA and the REDA.

This document does not apply to the following, non-exhaustive, list of medical devices:

- unlicensed Class II, III or IV medical devices;
- medical devices that are already imported into Canada and under the control of the CBSA;
- raw material

- medical devices requiring corrective measures other than relabelling.

3.0 Instructions on applying for Advance Notice of Importation

Timeframe for invoking section 21.1 of the MDR and section 3.1 of the REDR

A notice invoking section 21.1 of the MDR or section 3.1 of the REDR for radiation emitting devices must be received by HC prior to the importation of medical device(s) that require relabelling. For this purpose, importers holding an establishment licence or otherwise the manufacturers of the device may use the Advance Notice of Importation Form. A copy of the ANI Form can be requested by contacting hc.importnotice-avis.sc@canada.ca

Because the CBSA may request an admissibility recommendation from HC, HC recommends that an Advance Notice of Importation be submitted well before an anticipated importation of product.

Validity Period of the ANI and Time Period for Relabelling

An ANI Form submitted to HC will be considered active for the time frame specified in the form (maximum period of three months). During this period, an importer may import a medical device listed in a submitted ANI Form multiple times, without having to notify HC about each importation. Relabelling must still occur within three months of the date of importation. Failure to relabel within 3 months of importation may result in compliance and enforcement action.

Who is Responsible to Submit the ANI Form

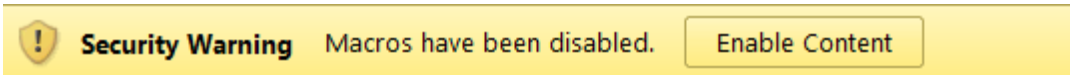
Either the manufacturer or the importer must submit the ANI Form, depending on the following:

- **If the medical device importer holds a valid Medical Device Establishment Licence (MDEL)**, the importer is responsible for submission of the ANI Form to HC.
- **If the medical device importer does not hold a valid MDEL (e.g. retailer or healthcare facility)**, the manufacturer is responsible for submission of the ANI Form to HC.
- **In all cases**, the manufacturer is responsible for submitting written notice to HC where they have authorised a party to conduct relabelling activities in Canada on their behalf. **Important Note:** Failure to provide this written notice may result in the ANI Form application being rejected.

4.0 Instructions for completing the Form

Please request a copy of the ANI Form by contacting hc.importnotice-avis.sc@canada.ca

You may see a security warning on the top left corner of the ANI Form. Make sure to enable macros to be able to complete and save the Form.



Part 1 – Manufacturer

Boxes 1.1 to 1.6: The manufacturer is the responsible party with respect to regulatory labelling requirements (see definition of manufacturer in Appendix A). Indicate the full legal business name and a complete mailing address.

Boxes 1.7 to 1.10: Indicate the name, title and contact information of the person responsible for the ANI. This person should be able to answer questions from HC inspectors, should there be a need for further information in order for HC to make a determination in accordance with the applicable sections of the MDR and REDR.

Box 1.11: Indicate the Medical Device Establishment Licence/Company ID number, if applicable.

Part 2 – Importation

Complete boxes 2.1 and 2.2 or 2.3 as follows:

> Boxes 2.1 and 2.2: If the ANI Form is being used for multiple importations, indicate the beginning and end date of the period during which the products to be relabelled will be imported. **The period cannot exceed three months**. It is not necessary to indicate specific importation dates for multiple importations. If further importations are anticipated after the expiration of the three month period, a new ANI Form must be submitted;
>
> or;
>
> Box 2.3: If the ANI Form is to be used for a single importation, indicate the anticipated importation date into Canada.

Important Note: Regardless of importation type, all ANI medical devices must be relabelled in accordance with the Acts, MDR and REDR within three months of importation.

Box 2.4: Indicate all Canadian ports of entry through which the medical device(s) may enter into Canada. Up to three ports of entry may be selected from the three drop down menus. If not listed, manually enter the port of entry at the bottom of box 2.4. If there are more than three ports of entry, choose two ports from the first two drop down menus and manually enter the names of the other ports of entry in the third drop down menu at the bottom of box 2.4. If the port of entry is unknown when completing the ANI Form, select “Unknown” from the drop down menu.

Part 3 – Importer

Boxes 3.1 to 3.5: The importer must be located in Canada and may include, for example, health care facilities, retailers and distributors. Indicate the full legal business name and a complete mailing address. **Important Note:** The importer must hold an MDEL unless exempted under S.44(2) of the MDR.

Boxes 3.6 to 3.9: Indicate the name, title and contact information of the person responsible for the ANI Form. This person should be able to answer questions related to the importation to assist HC inspectors make a determination in accordance with section 21.1 of the MDR and section 3.1 of the REDR.

Box 3.10: Indicate the Medical Device Establishment Licence/Company ID number, if applicable.

Part 4 – Company Designated by Manufacturer to relabel product

Box 4.1: When the importer listed in Part 3 is also the company conducting the relabelling on behalf of the manufacturer, check the "Same as Importer" box.

When the Manufacturer listed in Part 1 is also conducting the relabelling in Canada, check the "Same as Manufacturer" box.

Boxes 4.2 to 4.7: If another company will be relabelling on behalf of the manufacturer, indicate its full legal business name and its complete mailing address.

Boxes 4.8 to 4.11: Indicate the name, title and contact information of the responsible person with the designated company. This person should be able to answer questions related to the relabelling of the imported devices to assist HC inspectors to make a determination in accordance with section 21.1 of the MDR and section 3.1 of the REDR.

Box 4.12: Indicate the Medical Device Establishment Licence/Company ID number if applicable.

Box 4.13: As per section 21.2 of the MDR, if the manufacturer of the device is not performing the relabelling and has authorized the importer or a third party to relabel the device on its behalf, then the manufacturer must notify the Minister in writing of the name of the person who will be responsible for relabelling the device in Canada. Should this be the case, select "Yes" in box 4.13 and attach the manufacturer's notice to the email submission of this form.

Important Note: HC inspectors may monitor the medical devices at the location where they are being stored and/or relabelled.

Part 5 – Device Description

This section contains information on the medical device to be relabelled and may be duplicated to list several medical devices in the same ANI Form. This section can be duplicated by clicking the "Add Product" button located at the bottom of Part 5.

Box 5.1: Indicate the full name of the medical device, including its brand, at the time of importation.

Box 5.2: Indicate the approximate total quantity of medical devices to be imported within the time frame indicated in Part 2.

Box 5.3: Indicate the approximate intended date(s) of label correction.

Box 5.4: Indicate the HC-issued medical device ID number, if known.

Box 5.5: Select the medical device class from the drop-down list.

Box 5.6: If the imported medical device is a class II, III or IV, indicate its HC issued device licence number.

Box 5.7: Indicate the control or lot number of the medical device, if applicable.

Box 5.8: Indicate the medical device identifier(s).

Box 5.9: Describe the proposed labeling correction, along with a reference to the relevant labelling requirements of the MDR and/or REDR. Refer to Appendix B for assistance in identifying the associated provision for each label correction. Indicate one label correction per row.

Commitment

The Commitment section should be read and completed by a person in authority with the company responsible for submitting the ANI Form. The person in authority will be responsible for ensuring that the conditions set forth are followed and confirm to their understanding of the consequences of failing to respect the Terms and Conditions specified in Section 6 of this document.

Boxes C.1 and C.2: Indicate the name and title of the person in authority in these boxes. Note that this person may differ from the person indicated in box 1.6 (manufacturer submission) or 3.6 (importer submission).

Box C.3: The person in authority must check box C.3 to indicate that they have read and agree to the Terms and Conditions specified in Section 6 of this document.

Box C.4: Indicate the date the person in authority read and agreed to the Terms and Conditions specified in Section 6 of this document.

Instructions for submitting the form

Save an electronic copy of the ANI Form in .xlsm format and submit by email to hc.importnotice-avis.sc@canada.ca. If the manufacturer has authorized a third party to perform the labelling modification on their behalf, attach the manufacturer's written authorization, including the name, address and contact information of the person performing the relabeling. This information must match Part 4 of the ANI Form (Company Designated by Manufacturer to relabel product).
Upon receipt of a completed ANI Form, HC will send an acknowledgement of receipt to the contact name for the submitter identified in the form (dependent on whether the manufacturer or importer has submitted the ANI Form). **Please note that this acknowledgement does not constitute approval of the ANI application nor does it approve the medical device for sale in Canada.**

It is recommended that a copy of the ANI Form be retained in your records.

5.0 Terms and Conditions

The use of any language implying that the medical device has been verified or approved by HC or the Government of Canada may not be used in any marketing, advertising or promotional materials.

It is the responsibility of the manufacturer to ensure that all medical devices they wish to market in Canada meet the requirements of the FDA and MDR. HC may conduct inspections to verify compliance with the FDA, MDR, REDA and REDR at any time after the importation to determine whether the sale of the products will be lawful in Canada. HC may also communicate with importers and manufacturers at any time if additional information is required for this purpose.

If an importer or manufacturer fails to meet any of the conditions in this section, HC may deem the ANI invalid and take compliance and enforcement action in accordance with the *Compliance and Enforcement Policy for Health Products* (POL-0001). Compliance and enforcement action includes, but is not limited to: a stop sale order, refusal at the border, seizure, or destruction.

If a medical device that is subject to an ANI is referred to HC by the CBSA, HC will make an admissibility recommendation to the CBSA. A recommendation of refusal may be issued by HC for any of the following (non-exhaustive) reasons:

- A non-compliant medical device for which an ANI Form has not already been received;
- A non-compliant medical device which cannot be corrected by relabelling;
- A medical device for which the ANI has expired;
- A medical device for which the proposed relabelling is inadequate or not covered by the ANI.

6.0 Contact information and References

Contact

For further information, you may contact hc.importnotice-avis.sc@canada.ca

References

Food and Drugs Act, *Radiation Emitting Devices Act* and Associated Regulations
http://laws.justice.gc.ca

Health Canada Medical Devices Webpage
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.html

Medical Device Guidance Documents
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents.html

Guidance for the Labelling of Medical Devices (Not Including In Vitro Diagnostic Devices)
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-labelling-medical-devices-including-vitro-diagnostic-devices-appendices.html

Labelling of In Vitro Diagnostic Devices (Guidance Document)
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-labelling-vitro-diagnostic-devices.html

Appendix A

Key Definitions and Acronyms

Definitions in the Acts, MDR and REDR

device means an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in:

(a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,

(b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,

(c) diagnosing pregnancy in human beings or animals,

(d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or

(e) preventing conception in human beings or animals;

however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal;

directions for use, in respect of a medical device, means full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contra-indications and possible adverse effects;

identifier means a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices;

label includes a legend, word or mark that is or is to be applied or attached to or included in, or that accompanies or is to accompany, a radiation emitting device or a package;

lease **(REDA)** includes offer to lease and have in possession for the purpose of leasing;

manufacturer means a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf; or, a person engaged in the business of manufacturing radiation emitting devices or of modifying or assembling, to any extent, radiation emitting devices;

***package* (REDA)** includes anything in which a radiation emitting device is wholly or partly contained, placed or packed;

radiation means energy in the form of electromagnetic waves or acoustical waves;

radiation emitting device means:

(a) any device that is capable of producing and emitting radiation, and

(b) any component of or accessory to a device described in paragraph (a);

***sell* (FDA)** includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

***sell* (REDA)** includes offer for sale, have in possession for sale, deliver for sale, and distribute.

Acronyms

CBSA: Canada Border Services Agency

FDA: *Food and Drugs Act*

HC: Health Canada

MD: Medical Device

MDL: Medical Device Licence

MDEL: Medical Device Establishment Licence

MDR: *Medical Devices Regulations*

REDA: *Radiation Emitting Devices Act*

REDR: *Radiation Emitting Devices Regulations*

Appendix B

Medical Devices Regulations and Radiation Emitting Devices Regulations labelling provisions

This appendix will assist in matching label corrections to their associated provisions under the MDR and RDER. If a proposed labelling correction does not relate to any of the following provisions, please manually enter the reason into box 5.9 of the ANI Form.

Medical Devices Regulations

21 (1) No person shall import or sell a medical device unless the device has a label that sets out the following information:

(a) the name of the device;

(b) the name and address of the manufacturer;

(c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;

(d) in the case of a Class III or IV device, the control number;

(e) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units;

(f) the word "Sterile", if the manufacturer intends the device to be sold in a sterile condition;

(g) the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;

(h) unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, as well as the performance specifications of the device if those specifications are necessary for proper use;

(i) the directions for use, unless directions are not required

(i) in the case of a decorative contact lens, for the device to be used safely, and

(ii) in the case of any other medical device, for the device to be used safely and effectively; and

(j) any special storage conditions applicable to the device.

(2) The information required pursuant to subsection (1) shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.

22 (1) Subject to subsection (2), if a medical device is intended to be sold to the general public, the information required by subsection 21(1) shall

(a) be set out on the outside of the package that contains the device; and

(b) be visible under normal conditions of sale.

(2) Where a package that contains a medical device is too small to display all the information in accordance with section 21, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale.

23 (1) Subject to subsection (3), the information required by subsection 21(1) shall, as a minimum, be in either English or French.
(2) Subject to subsection (3), where the directions for use are supplied in only one official language at the time of sale, directions for use in the other official language shall be made available by the manufacturer as soon as possible at the request of the purchaser.
(3) In respect of a medical device to be sold to the general public, the information required by paragraphs 21(1)(a) and (e) to (j) shall, as a minimum, be in both English and French.

Other: If there are other labelling changes not corresponding to any of the above.

Radiation Emitting Devices Regulations

Schedule II, Part II Dental X-Ray Equipment

S. 2: The manufacturer, distributor and importer must ensure that all of the following **information accompanies each piece of dental X-ray equipment**:

(a) the **manufacturer's name and civic address**, and its postal address if different;
(b) the **model** designation of the equipment;
(c) the **installation instructions**;
(d) any **radiological safety procedures and additional precautions** that are necessary because of any unique features of the equipment;
(e) **instructions for use** that include
 (i) a description of the influence of the main settings or selections that are available to the operator on the radiation dose to the patient,
 (ii) if protection of the operator is affected by distance from the equipment, information on the impact of distance on the radiation dose, and
 (iii) all information necessary to minimize the operator's exposure to radiation;
(f) **maintenance instructions**;
(g) **procedures for quality control testing** to be performed on the equipment, including how often the tests are to be performed and the acceptance criteria;
(h) for **each X-ray tube assembly**,
 (i) the nominal focal spot sizes,
 (ii) the cooling curves for the anode and for the X-ray tube housing,
 (iii) the X-ray tube rating charts, and
 (iv) the focal spot position;
 (i) the **duty cycles**, its rectification type and its generator rating;
(j) the **nominal line voltage**, the **maximum line current** and the **line voltage regulation** that are necessary to operate the equipment at the maximum line current;
(k) the **loading factors** that constitute the **maximum line current condition** for the X-ray generator;
(l) the recommended **loading factors** for each patient size;
(m) when combinations of loading factors are indicated on the control panel by either a single reference to the combination or the value of only one of the loading factors that makes up the combination, the **values of all the loading factors for each combination**;
(n) if the equipment can operate in **automatic exposure control mode**,

(i) the accuracy limits of the automatic exposure control,
(ii) the nominal shortest irradiation time in that mode, and
(iii) the reproducibility of the air kerma relative to the range of loading factors, as the loading factors are adjusted by the automatic exposure control;

(o) if the equipment can operate in a mode other than automatic exposure control mode, the **operating range and the maximum deviation for any setting** within the operating range for each loading factor;

(p) if the equipment is battery-powered, the **minimum state of charge** that is necessary for it to operate;

(q) if **removable protective devices** are specified for use with the equipment by the manufacturer, information about their effectiveness, application and use;

(r) if **dosimetric indications** are displayed on the equipment, information and instructions on how to check and maintain their accuracy; and

(s) for transportable equipment, **recommendations for secure storage** of the equipment against theft and unauthorized use.

S.3 In addition to the requirements set out in section 2, the manufacturer, distributor and importer must ensure that all of the following additional **information accompanies each piece of intra-oral dental X-ray equipment**:

(a) the shape and dimensions of the **exit field**;

(b) in the case of equipment that has **a digital X-ray image receptor**,
(i) a description of the **minimum performance criteria** for the device that is used to display the images for diagnostic purposes,
(ii) the **nominal X-ray image receptor air kerma range** that is needed for the intended use, and
(iii) recommendations for **typical loading factors** at specified distances between the focal spot and the skin to achieve the air kerma referred to in subparagraph (ii);

(c) the **method** by which the **distance between the focal spot and the skin can be determined** using the indicator specified in paragraph 7(f);

(d) if the **air kerma** is indicated on the equipment, the **maximum deviation**;

(e) if the air kerma is not indicated on the equipment,
(i) the **air kerma at a given distance from the focal spot** for every selectable combination of loading factors, and
(ii) the **maximum deviation of the air kerma**;

(f) a **method** to calculate the **dose area product** using the air kerma and the exit field size; and

(g) in the case of hand-held equipment,
(i) **values for the leakage radiation** at the operator's position and the method to assess the leakage radiation,
(ii) **guidance on how to avoid image degradation** caused by motion of the X-ray source assembly during loading and the methods to assess the degradation, and
(iii) the designation of a **significant zone of occupancy**, as follows:
(A) **dimensions** of at least 60 cm x 60 cm with a height of at least 200 cm,
(B) **a drawing** that indicates the boundaries of the zone in relation to clearly recognizable features of the equipment,
(C) at least one **profile of stray radiation** in the zone with respect to the height above the floor — under representative operating conditions indicated — and that includes the point that receives the highest dose, and

(D) a **description of the testing methodology** used to determine the profiles of stray radiation, including instructions for achieving the loading factors used in the testing if they are controlled only by an automatic control system.

S.4 In addition to the requirements set out in section 2, the manufacturer, distributor and importer must ensure that all of the following **additional information accompanies each piece of extra-oral dental X-ray equipment**:

(a) a **description of the geometric relationship** between the focal spot, X-ray beam dimensions, patient position and image reception area;

(b) if the **air kerma** is indicated on the equipment, the **maximum deviation**;

(c) if the air kerma is not indicated on the equipment,

(i) the **air kerma at the entrance of the X-ray image receptor** for every selectable combination of loading factors, and

(ii) the **maximum deviation of the air kerma**;

(d) the **maximum deviation of the dose area product**;

(e) **instructions** on how to identify the location and dimensions of the **effective image reception area**;

(f) for equipment in which any of the loading factors set out in items 1 to 3 and 5, column 1, of the table to subsection 30(1) vary during an irradiation, instructions on **how to measure the deviation** and on **how to compare it with the maximum deviation** set out in column 2 of that table; and

(g) if a precalculated or measured current time product is indicated on the equipment, the lowest current time product or the combinations of loading factors that result in the **lowest current time product**.

S.6 : The manufacturer must ensure that all **controls**, **warning lights** and **other indicators on the control panel** are clearly **labelled as to their function**. (function of controls)

S.7 : The manufacturer must ensure that all of the following **information is displayed** on dental X-ray equipment:

(a) on the external surface of the **control panel,**

(i) a **statement that unauthorized use of the equipment is prohibited**,

(ii) a **warning that hazardous X-rays are emitted** when the equipment is in use, and

(iii) one of the **X-ray warning symbols** set out in section 8;

(b) on an external surface of the **equipment**,

(i) the **name of its manufacturer**,

(ii) its **model designation**,

(iii) its **serial number**,

(iv) the **date of its manufacture**, and

(v) the **country where it was manufactured**;

(c) on or near the external surface of the control panel — when combinations of loading factors are indicated on the control panel by either a single reference to the combination or the value of only one of the loading factors that makes up the combination — **the values of all the loading factors for each combination**;

(d) on the external surface of the X-ray source assembly, **with respect to the X-ray tube**,

(i) the **name of its manufacturer,**
(ii) the **model designation**,
(iii) its **serial number**, and
(iv) the **country of its manufacture**;

(e) on the external surface of the X-ray source assembly, **the permanent filtration of the X-ray source assembly**, expressed at a specified X-ray tube voltage either in millimetres of aluminum equivalent or as the thickness of any other material, together with its chemical symbol;

(f) on the external surface of the X-ray source assembly**, a mark that indicates the location along the X-ray beam axis of the focal spot on the anode target**;

(g) on the surface of any detachable beam-limiting device,

(i) the **name of its manufacturer**,
(ii) its **model designation**,
(iii) its **serial number**,
(iv) its **quality equivalent filtration**, if it is more than 0.2 mm aluminum equivalent, expressed at a specified X-ray tube voltage either in millimetres of aluminum equivalent or as the thickness of another material together with its chemical symbol, and
(v) in the case of intra-oral equipment, its **exit field size**;

(h) on the external surface of every fixed layer of material in the path of the X-ray beam incident on the patient — excluding any added filters and non-removable materials in the X-ray tube assembly — **the quality equivalent filtration**, if it is more than 0.2 mm aluminum equivalent, expressed at a specified X-ray tube voltage either in millimetres of aluminum equivalent or as the thickness of another material together with its chemical symbols; and

(i) on the external surface of the X-ray tube housing of hand-held intra-oral equipment, the words

"**WARNING**: Hand-held operation increases operator radiation exposure due to proximity. See manufacturer safety information."
« ATTENTION : L'utilisation de l'appareil en mode portatif augmente l'exposition de l'opérateur au rayonnement en raison de la proximité. Consultez les renseignements de sécurité du fabricant. »

S.8 : **The X-ray warning symbol** must have the following **characteristics**:

(a) it must be displayed in two contrasting colours;
(b) it must be visible and identifiable from a distance of 1 m;
(c) it must be at least 2 cm high and at least 2 cm wide;
(d) it must bear the words "CAUTION: X-RAYS — ATTENTION : RAYONS X"; and
(e) it must conform **to one** of the following:

(i) the X-ray warning symbol
(ii) the symbol ISO 361 in the report of the International Electrotechnical Commission entitled Graphical symbols for electrical equipment in medical practice, Publication IEC TR 60878: 2015, Third Edition
(iii) the symbol ISO 7010-W003 in the report of the International Electrotechnical Commission entitled Graphical symbols for electrical equipment in medical practice, Publication IEC TR 60878: 2015, Third Edition

Schedule II, Part XII: Diagnostic X-Ray Equipment

S.2 The manufacturer must ensure that the **following information accompanies each piece of diagnostic X-ray** equipment:

(a) the **installation instructions**;
(b) the **address of the manufacturer**;
(c) **any radiological safety procedures** and **additional precautions** that are necessary because of any unique features of the equipment;
(d) the **maintenance instructions** necessary to keep the equipment in compliance with the requirements of this Part;
(e) the **rated line voltage**, the **maximum line current** and the **line voltage regulation** for the operation of the equipment at the maximum line current;
(f) the **loading factors** that constitute the maximum line current condition for the X-ray generator;
(g) for each X-ray tube assembly,
    (i) the nominal focal spot sizes and the method of their determination,
    (ii) the cooling curves for the anode and for the X-ray tube housing,
    (iii) the X-ray tube rating charts, and
    (iv) the method by which the focal spot to image receptor distance can be determined using the indicator specified in subparagraph 3(c)(i);
(h) its **duty cycles**, **rectification type** and **generator rating**;
(i) if the equipment is battery powered, the **minimum state of charge** necessary for it to operate;
(j) the **operating range of X-ray tube voltages** and the **maximum deviation** for any selected X-ray tube voltage within that range of values;
(k) if the equipment is not operated exclusively in automatic exposure control mode, the **accuracy limits** of
    (i) the controlling timer,
    (ii) the X-ray tube current, and
    (iii) the current time product;
(l) where the equipment operates under automatic exposure control, the **accuracy limits** of that control; and
(m) the **conditions under which the information provided under paragraphs (j) to (l) is valid**.

S.3: Diagnostic X-ray equipment must **display** the following information in a manner that is legible, permanent and visible on the specified surfaces:

(a) on the external surface of the **main control panel**
        (i) a **statement prohibiting unauthorized use** and **warning that hazardous X-rays are emitted** when the equipment is in operation,
    (ii) the **X-ray warning symbol** described in section 4, and
    (iii) with respect to the **X-ray generator**,
        (A) the **name of the manufacturer**,
        (B) the **model designation**,
        (C) the **serial number**,
        (D) the **date of manufacture**, and
        (E) the **country of manufacture**;
(b) on the external surface of the X-ray tube housing, with respect to the **X-ray tube assembly**,
        (i) the **name of the manufacturer**,
        (ii) the **model designation**,
        (iii) the **serial number**,

(iv) the **date of installation of the X-ray tube** in the X-ray tube housing,
(v) the **country of manufacture**, and
(vi) the **minimum permanent inherent filtration of the X-ray beam** emitted from the X-ray tube assembly, expressed in millimetres of aluminum equivalent at a specified X-ray tube voltage;

(c) on the **external surface of the X-ray tube housing** or another suitable structure permanently attached to the X-ray tube housing

(i) an **indicator that enables the focal spot to image receptor distance to be determined** to within 2% of that distance, and
(ii) if the X-ray tube and the X-ray generator are not located within a common enclosure, **marks that clearly indicate the anode and cathode terminals** on the X-ray tube housing and on the high-voltage generator; and

(d) on the **external surface of any beam limiting device** that adds filtration to the X-ray beam, the **total permanent filtration** deliverable by the beam limiting device, expressed in millimetres of aluminum equivalent at a specified X-ray tube voltage

S.4 : The **X-ray warning symbol** shall:

(a) be displayed in two contrasting colours;
(b) be visible and identifiable from a distance of 1 m;
(c) be at least 2 cm high and at least 2 cm wide;
(d) bear the words "CAUTION: X-RAYS — ATTENTION : RAYONS X"; and
(e) **conform to**

(i) the following diagram:
or
(ii) symbol 03-03 in the report of the International Electrotechnical Commission entitled Graphical symbols for electrical equipment in medical practice, Publication 878, 1988, illustrated as follows:

S.5 : All **controls, meters, warning lights** and **other indicators** required by this Part must be clearly **labelled as to their function.**

<u>Schedule II, Part XIII: Ultrasound Therapy Devices</u>

S.2 : Every ultrasound therapy device shall be designed in such a manner that

(b) all user **controls, meters, lights** or **other indicators** are clearly visible, readily discernible and clearly **labelled to indicate their function.**

S.3 : Every ultrasound therapy device shall bear

(a) on the **external surface of its housing**

(i) the **name and address of the manufacturer**,
(ii) the **name and address of the distributor**, if the distributor is not the manufacturer,
(iii) the **type and model designation**,
(iv) the **serial number**,
(v) the **month and year of manufacture**,
(vi) the **ultrasonic frequencies** in kilohertz (kHz) or megahertz (mHz),

(vii) a statement indicating whether **the wave produced by the device** is a continuous wave or an amplitude modulated wave,

(viii) in the case of a device that produces an **amplitude modulated wave**,

(A) the pulse repetition rate, the pulse duration, the ratio of the temporal maximum effective ultrasonic intensity to the temporal average effective ultrasonic intensity, and a description of the wave shape, where these parameters do not vary depending on the power, and

(B) the pulse repetition rate, the pulse duration, the ratio of the temporal maximum effective ultrasonic intensity to the temporal average effective ultrasonic intensity, and a description of the wave shape, all at temporal maximum ultrasonic power where these parameters do vary depending on the power,

(ix) the **line voltage** used for normal operation, and

(x) the **ultrasound radiation warning sign** described in section 4; and

(b) on the **external surface of each applicator**

(i) the **identification of the type and model** of the ultrasound therapy device for which it is designed,

(ii) where an applicator is a focussing applicator, the **focal length** and the **focal area**,

(iii) a unique **serial number** or other unique identification, and

(iv) the **effective radiating area** in square centimetres (cm2).

S.4 : The **warning sign** referred to in subparagraph 2(3)(a)(x) is a sign that

(a) is shown in two contrasting colours;

(b) is clearly visible and identifiable from a distance of 1 m;

(c) has no outer dimensions less than 2 cm;

(d) bears the words “CAUTION-ULTRASOUND, ATTENTION-ULTRASONS”; and

(e) is designed **in accordance** with the following diagram:

Other: If there are other labelling changes not corresponding to any of the above.