Guidance on how to complete the application for a new medical device licence

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Canada

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This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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Overview

Medical devices are classified into one of 4 classes. Class I represents the lowest risk and Class IV represents the highest risk.

Class II, III and IV medical devices must be licenced before they may be imported or sold in Canada.

A licence is issued to the device manufacturer for each application submitted, provided the requirements of the *Medical Devices Regulations* are met.

Policy objective

This guidance provides information to manufacturers and regulatory correspondents on how to complete an application form for a new medical device licence.

Scope and application

This guidance applies to all new Class II, III and IV medical devices.

Note about guidance documents in general

Guidance documents provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied by industry. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy or quality of a therapeutic product. We must make sure that such requests are justifiable and that decisions are clearly documented.

Health Canada has also published a guidance document to help manufacturers prepare applications submitted under the Interim Order (IO).

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

Definitions

Bisphenol A [BPA; Phenol, 4,4' -(1-methylethylidene)bis-]: An industrial raw material that was identified for screening assessment under the *Canadian Environmental Protection Act*. BPA is mainly used as a raw material in the production of polycarbonates and epoxy resins. BPA or BPA-based polymers are used in the manufacture of a variety of medical devices, including resin-based dental composite restorative and prosthodontic materials, dental sealants, hemodialyzers, hemofilters and blood oxygenators.

Please refer to Appendix 1, Table 1 for the chemical identity of BPA, including its Chemical Abstracts Services (CAS) registry number and synonyms.

Device ID: Refers to the device identification number assigned by Health Canada.

DI(2-Ethylhexyl) Phthalate (DEHP) is a chemical additive that is used to make polyvinyl chloride (PVC) soft, flexible and kink-resistant. PVC plasticized with DEHP is currently used in a variety of medical devices, including blood bags, catheters, intravenous tubing and medical gloves.

A medical device is considered to contain DEHP if the amount of DEHP in the device is more than or equal to 0.1% of the device's mass (that is, ≥0.1% w/w).

Please see Appendix 2, Table 2 for the chemical identity of DEHP, including its Chemical Abstracts Services (CAS) registry number, synonyms and known trade names.

Medical device: A device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.

Identifier: 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. Examples of an identifier for a device are a catalogue, model or part number.

Licence application type: The application may be submitted as a single device, system, test kit, device group, device family or device group family. The term "test kit" applies only to in vitro diagnostic devices. For more information on licence application types, see the guidance for interpreting sections 28 to 31: licence application type.

Manufacturer: A person who:

- sells the medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person and
- is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose

These tasks may be performed by that person or on their behalf. “Person” includes a partnership, firm or association.

Near patient *in vitro* diagnostic device (IVDD): Is intended for use outside a laboratory, for testing at home or at the point-of-care, such as a pharmacy, a health care professional’s office or the bedside.

Guidance for implementation

When a new medical device licence is required

Under the *Medical Devices Regulations*, a new device licence is a pre-market requirement for:

- any new device that was imported or sold in Canada after July 1, 1998
- a licensed device whose licence type is being modified from the type in the original licence application (see the guidance for interpreting sections 28 to 31: licence application type)
- a device previously authorized for sale for investigational testing, or under the special access provisions of the *Regulation*s, that is now to be offered for general sale

Applying for a medical device licence

Device classification

The rules to classify medical devices are outlined in Schedule 1 (Parts 1 and 2) of the *Regulations*. Part 1 of Schedule 1 addresses medical devices other than in vitro diagnostics. Part 2 addresses in vitro diagnostic devices.

For further guidance on the classification of medical devices, see the:

- guidance on the risk-based classification system for non-in vitro diagnostic devices or
- guidance for the risk-based classification system of in vitro diagnostic devices

After ascertaining the class of the device, use the appropriate application form:

- New Class II Medical Device Licence Application Form
- New Class III Medical Device Licence Application Form
- New Class IV Medical Device Licence Application Form

The keyword index to assist manufacturers in verifying the class of medical devices is an alphabetical listing of all the short descriptors for devices that are entered into the medical devices system. This document contains synonyms and industry words that are used to describe these devices, along with their respective classifications.

Item 1: Name of the device (as it appears on the label)

The device name indicated for a system, medical device family or medical device group family must appear, at least in part, on the label of each member device. Only one name is to be entered in Item 1. The device name on the application form will be used as the licence name unless the application is for a family of medical devices. In this case, a generic licence name that covers all possible trade names (for example, urinary catheters) should be used.

The licence name usually reflects the types of devices that are contained within the licence and sometimes may vary from the device name.

Item 2: Manufacturer information (as it appears on the label)

This is the name and address of the manufacturer of the device and the name and address to which the licence will be issued. A complete address must include:

- name and title of a contact person (contact person at the location of the legal "manufacturer")
- company ID (if known, this number is assigned by Health Canada)
- telephone number, fax number and email address of the contact person
- street name and number or post office box
- city, province or state
- postal or zip code
- country

Item 3: Regulatory correspondent information

All regulatory correspondence will be sent to this address (if different from Item 2), but the licence will be issued to the manufacturer. A third party may submit a medical device licence application. The mailing address and name of this authorized regulatory correspondent will be entered here.

Item 4: Invoicing information

Enter the name, address and contact information of the party that will receive all invoicing and billing information. This person may be the same as in Items 2 or 3, or it may be a third party.

Item 5: Quality management system certificate

Enter the certificate number and the name of the recognized registrar that has issued the certificate. A legible copy of the certificate must accompany each medical device licence application. For more information on the content and acceptance of quality management

system certificates, please see the guidance on the content of ISO 13485 quality management system certificates issued by Health Canada recognized registrars (GD207). The certificate must be issued by a Health Canada-recognized registrar. Please see the current list of recognized registrars.

Item 6: Attestations

Class II licence applications

Attestation of compliance with the applicable requirements of sections 10 to 20

Manufacturers of Class II medical devices must attest that they have objective evidence establishing that they are compliant with section 10, subsections 11(1) and 12(1) and sections 13 to 20 of the *Regulations*.

For decorative contact lenses, manufacturers must attest that they have objective evidence establishing that they meet section 10, subsections 11(2) and 12(2) and sections 13 to 17 of the *Regulations*.

Attestation of investigational testing for in vitro diagnostic devices (IVDDs)

Manufacturers of Class II near patient IVDDs must attest that investigational testing of their device was conducted:

- using human subjects representative of the intended patients and
- under conditions similar to the intended conditions of use of the device

Near patient attestation

Manufacturers must attest that the device is **not** a near patient IVDD, if applicable.

Signature

The manufacturer of the device must sign and date the application.

Class III and IV licence applications

Attestation section

Along with the application form, a manufacturer must attest that the information requested in section 32, subsection (3) or (4) of the *Regulations* is complete. Please refer also to the:

- guidance on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including in vitro diagnostic devices (IVDDs)
- draft Health Canada IMDRF table of contents for medical devices applications guidance

Signature

The manufacturer of the device must sign and date the application.

Item 7: Purpose or intended use of device

Information in this item is crucial to establishing the appropriate device class. It should include the following:

- intended purpose, indications for use, conditions for which the device is used
    - the intended use statement should be verbatim as it appears on the device labelling
- patient population for which the device is intended, including age range, if applicable, and specific diagnoses
- anatomical and physiological particulars related to the patient using the device, if applicable
- whether the device uses an energy source and whether energy is transferred to the patient
- the document, document version number and date where the formal intended use appears

For licence amendments, if there are changes to the instructions for use/package insert, a red-lined version of the revised pages should be submitted. A clean copy of the latest version of the IFU/PI should also be submitted with the application.

Item 8: Licence application type

A manufacturer may apply for the following types of device licence:

- Single medical device: Defined by a unique device name, sold as a distinctly packaged entity and does not meet the criteria for a medical device group, medical device family, medical device group family, system or test kit, and may be offered in a range of package sizes
    - examples include an acupuncture needle, aneurysm clip, larynx prosthesis or dental cement
- Medical device family: A group of medical devices made by the same manufacturer that differ only in shape, colour, flavour or size, have the same design and manufacturing process and have the same intended use
    - examples include intra vascular catheters, insulin syringes, feeding tubes or vascular access grafts
- Medical device group: A collection of medical devices, such as a procedure pack or tray, that is sold under a single name
    - examples include a denture repair kit, de-clotting tray, parenteral administration kit or disposable circumcision tray
- Medical device group family: A collection of medical device groups that are made by the same manufacturer, have the same generic name specifying their intended use and differ only in the number and combination of products that comprise each group
    - examples include intravenous (IV) administration sets, dressing trays, contact lens care kits or irrigation trays
- System: A medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name and manufactured by the same manufacturer
    - examples include hip prostheses, knee prostheses or ultrasonic imaging system
- Test kit: An *in vitro* diagnostic device that consists of reagents or articles, or any combination of these, and is intended to be used to conduct a specific test

For further assistance in ascertaining the appropriate licence application type for your product, please see the guidance for interpreting sections 28 to 31: licence application type.

Item 9: Place of use

Indicate on the application form by checking the appropriate boxes.

Item 10: Medical devices containing drugs

Non-IVD devices containing drugs

Do not complete Item 10 if the device is an IVDD.

If the device contains a drug or drug substance, **which includes a pharmaceutical or biological drug, or a natural health product**, specify its:

- brand or trade name
- active ingredient(s)
- manufacturer
- drug identification number (DIN) or natural product number (NPN)

Health Canada's Drug/Medical Device Combination Products Policy addresses the regulation of products that contain both a drug and medical device.

IVDD test kits containing controlled substances

If the device is a test kit containing a substance listed in Schedule I, II, III or IV of the *Controlled Drugs and Substances Act*, it would need to be registered with the Office of Controlled Substances.

For information on the process for applying for a test kit registration number, please see the Office of Controlled Substances.

Item 11: Device history

Indicate if the device has been previously authorized for sale in Canada under the investigational testing or special access provisions of the *Regulations*. A device that has been previously authorized for sale under the investigational testing provisions will have a device identification (ID) number. A device that has been previously authorized for sale under the special access provisions will have an authorization number. Please supply the appropriate number.

Item 12: Identifier of device

Only devices, components, parts and accessories listed on the application will be considered for licensing. Spare parts that do not represent medical devices on their own should not be listed. If additional space is required, photocopy the Item 12 page and attach it to the application form.

For a single device:

- Enter the name of the device in the first column.
- Enter the identifier for the device (bar code, catalogue, model or part number) in the second column.
- Check the third column if the device contains ≥0.1% by mass of DEHP.
- Check the fourth column if the device is manufactured from raw materials containing or derived from BPA.

For a medical device group, medical device family or medical device group family:

- List the names of the constituent members in the first column.
- Enter the associated identifiers in the second column.
- Check the associated row in the third column if a constituent member contains ≥0.1% by mass of DEHP.
- Check the associated row in the fourth column if a constituent member is manufactured from raw materials containing or derived from BPA.

Please refer to Health Canada's policy statement on the working definition for nanomaterial.

The working definition indicates that a nanomaterial is a material within 1 to 100 nanometers in at least one dimension. However, for the purposes of medical device licensing, the Medical Devices Directorate is requesting notification for devices containing nano-scale materials with a particle size between 1 and 1,000 nanometers.

Please identify the specific type of nano-scale material that is present in each device listed in the licence application. Examples of a specific type of nano-scale material could include:

- nano titanium dioxide
- nano silver
- quantum dots
- nano polymers
- nano glasses
- nano ceramics
- carbon nanotubes
- nano-fibres

The last column in the application is for Health Canada use only.

See the definitions of “BPA,” “DEHP” and “identifier” in this guidance document.

It is the manufacturer’s responsibility to determine whether a medical device contains ≥0.1% w/w of DEHP or is manufactured from raw materials containing or derived from BPA.

The absence of a checkmark in the third and fourth columns for a specific device will be taken to indicate the device:

- does not contain ≥0.1% w/w of DEHP or
- is not manufactured from raw materials containing or derived from BPA

Item 13: Compatibility of interdependent devices

For a device intended to be used with another Class II, III, or IV device, a list of all medical devices that this device is intended to be used or function with is required. Include their licence number as well. This requirement is intended to be for system components from the same manufacturer.

An important requirement in demonstrating compliance with the applicable requirements of sections 10 to 20 of all medical devices intended to be used together is compliance with section 18 of the *Regulation*s. Section 18 requires that when medical devices are intended to be used with other medical devices, they must:

- be compatible with every other medical device with which they interact and
- not adversely affect the performance of the combination of medical devices

Failure to submit compatibility information for interdependent medical devices may lead to delays in the pre-market review of device licence applications. The Medical Devices Directorate will need to request the necessary information. Manufacturers will also need to assemble the device and submit it for review.

Manufacturers are reminded that the submission of evidence of compatibility for inter-dependent medical devices is a requirement under the *Regulation*s.

See also the notice to industry, dated April 30, 2002, on the licensing requirements of interdependent medical devices.

Item 14: List of recognized standards complied with in the manufacture of the device

Refer to the guidance on the recognition and use of standards under the *Regulations*.

For Class II licence applications, the manufacturer is to list the recognized standards complied with. Alternatively, the manufacturer is to attest that they possess objective evidence that the device either:

- meets an equivalent or better standard or
- has been tested and alternate evidence of compliance with the applicable requirements of sections 10 to 20 exists

For Class III and IV licence applications, the manufacturer must respond "YES" where applicable and provide appropriate documentation:

- if the device conforms with recognized standards, the manufacturer may provide a "declaration of conformity form" indicating the standard(s) or submit detailed information as evidence of compliance
- if the device does not conform with the listed recognized standards, but meets an equivalent or better standard, the manufacturer may provide a "declaration of conformity form" to indicate these equivalent or better standards
- if the device does not conform with the listed recognized standards or does not meet an equivalent or better standard, the manufacturer is to include detailed information as evidence of compliance with the applicable requirements of sections 10 to 20

If the manufacturer does not comply with any of these 3 options, a licence will not be issued.

Item 15: Priority review

Manufacturers may complete this item if they wish to request a priority review for their application. Priority review will be granted to a Class III or IV medical device licence application intended for the diagnosis or treatment of a serious, life-threatening or severely debilitating disease or condition. There must be substantial clinical evidence that the medical device:

- provides effective treatment or diagnosis of a disease or condition for which no medical device is currently licensed in Canada
- provides significant risk-benefit improvement over existing therapeutic or diagnostic devices for a disease or condition that is not adequately managed by existing products marketed in Canada or
- responds to an unforeseen or unmet urgent health need (new)

Applications requesting priority review will be screened in accordance with the standard 15-day performance target. They will be reviewed in priority if they meet one of the above criteria. Depending on the complexity of the application or the novelty of the product, this might lead to a shorter time to market.

The current fees and service standards for reviewing Class III and IV licence applications will still apply (60 and 75 days). Applicants will be notified at screening acceptance whether their application was accepted for priority review.

Class II licence applications

Item 16: Review documents

Indicate which review documents listed in the table in the application form are included as attachments to the application.

For details on the content and format of labelling material for Class II medical devices, refer to the:

- guidance for labelling medical devices
- guidance for labelling in vitro diagnostic devices

For high-level disinfectant or sterilant solutions and/or contact lens disinfectants, manufacturers must provide either:

- an existing DIN for a marketed product or
- objective evidence to establish that this device meets section 10, subsections 11(1) and 12(1) and sections 13 to 20 of the *Regulations*

For details on the safety and effectiveness information required of high-level disinfectants and sterilants, please see the:

- guidance document on the safety and effectiveness requirements for high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices

For details on the safety and effectiveness information required of contact lens disinfectants, please see the:

- guidance document on the safety and effectiveness requirements for contact lens disinfectants

Item 17: Refer to the medical devices licence application fee form

Instructions are provided on the form. They must be carefully followed to avoid delays in application processing.

Please see the:

- guidance document on fees for the review of medical device licence applications

Class III licence applications

Item 16: Review documents

Indicate which review documents listed in the table in the application form are included as attachments to the application.

For details on the content and format of review documents for Class III and IV medical devices, please see the:

- guidance on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including in vitro diagnostic devices (IVDDs)
- draft Health Canada IMDRF table of contents for medical devices applications guidance

Items 17: Refer to the medical device licence application fee form

Instructions are provided on the form. They must be carefully followed to avoid delays in the processing of your application.

Please also see the:

- guidance document on fees for reviewing medical device applications

Class IV licence applications

Item 16: Review documents

Indicate which review documents listed in the table in the application form are included as attachments to your application.

For details on the content and format of review documents, please see the:

- guidance on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including in vitro diagnostic devices (IVDDs)
- draft Health Canada IMDRF table of contents for medical devices applications guidance

Item 17: Devices containing biological material

This section of the application form must be completed in detail. If more space is required, photocopy the page and attach it to the application form.

Items 18: Refer to the medical device licence application fee form

Instructions are provided on the form. They must be carefully followed to avoid delays in the processing of your application.

Please also see the:

- guidance document on fees for reviewing medical device applications

Before submitting a medical device licence application

Before submitting a new medical device licence application, make sure you:

a) Complete the device licence application form and fee form. You may choose to have a regulatory correspondent complete and submit the application on your behalf.
b) Sign the application form, certifying that all the information in the application is accurate and complete. A faxed copy of the manufacturer's signature or an e-signature is acceptable.
c) Submit the applicable licence fee for a Class II, III or IV medical device with the application when applicable or upon receipt of an invoice. For further information on timing, please see the guidance document on fees for the review of medical device licence applications.
d) Submit the quality management system certificate with the application.
e) Submit the licence application disclosure request with the application.

You or your regulatory correspondent may submit the application and any supporting documentation to:

Bureau of Licensing Services
Medical Devices Directorate
Health Canada
11 Holland Avenue
Address Locator 3002A
Ottawa ON K1A 0K9

Phone: 613-957-7285
Fax: 613-957-6345
Email: hc.devicelicensing-homologationinstruments.sc@canada.ca

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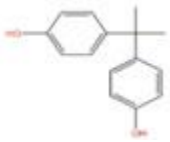
RTECS. February 2000. *Registry of Toxic Effects of Chemical Substances*. National Library of Medicine, National Toxicology Information Program, Bethesda, MD.

Appendix 1, table 1, chemical identity of Bisphenol A

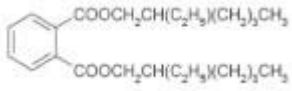
Characteristic	Information
Chemical Abstracts Services (CAS) Registry Number	80-05-7
Domestic Substances List name	phenol, 4,4' -(1-methylethylidene)bis-
National Chemical Inventories (NCI) names*	phenol, 4,4'-(1-methylethylidene)bis- (TSCA, PICCS, ASIA-PAC) 4,4'-isopropylidenediphenol (EINECS, PICCS) 2,2-Bis(4'-hydroxyphenyl) propane (ENCS) phenol, 4,4'-(1-methylethylidene)bis- (AICS, PICCS) 4,4'-(1-Methylethylidene)bisphenol (ECL) 4,4'-Bisphenol A (ECL) phenol, 4,4'-(1-methylethylidene)bis- (SWISS) bisphenol A (SWISS, PICCS) p,p'-isopropylidene diphenol (PICCS) diphenol methylethylidene (PICCS) bis[phenol], 4,4'-(1-methylethylidene)- (PICCS) bisphenol-a (PICCS) bisphenol, 4,4'-(1-methylethylidene)- (PICCS) 4,4-isopropylidene diphenyl (PICCS) 4,4'-dihydroxyphenyl-2,2-propane (PICCS) 2,2-di(4-hydroxyphenyl)propane (PICCS) 2,2-di(4-hydroxyphenyl) propane (PICCS) 2,2-bis-(4-hydroxy-phenyl)-propane (PICCS)
Other names	bisphenol A diphenylolpropane BPA
Chemical group	Discrete organics
Chemical subgroup	Phenols
Chemical formula	$C_{15}H_{16}O_2$

Characteristic	Information
Chemical structure	
SMILES	Oc(ccc(c1)C(c(ccc(O)c2)c2)(C)C)c1

*National Chemical Inventories (NCI) 2006:

- AICS (Australian Inventory of Chemical Substances)
- ASIA-PAC (Asia-Pacific Substances Lists)_Toc173920654
- ECL (Korean Existing Chemicals List)
- EINECS (European Inventory of Existing Commercial Chemical Substances)
- ENCS (Japanese Existing and New Chemical Substances)
- PICCS (Philippine Inventory of Chemicals and Chemical Substances)
- SWISS (Inventory of Newly Notified Substances and Giflist 1 - List of Toxic Substances)
- TSCA (Toxic Substances Control Act Chemical Substance Inventory)

Appendix 2, table 1, chemical identity of Di(2-Ethylhexyl) Phthalate

Characteristic	Information	Reference
Chemical name	di(2-ethylhexyl) phthalate	RTECS 2000
Synonyms	DEHP dioctylphthalate bis(2-ethylhexyl) phthalate	RTECS 2000
Registered trade names	Bisoflex 81 Eviplast 80 Octoil Plantinol DOP Staflex DOP	RTECS 2000
Chemical formula	$C_{24}H_{38}O_4$	RTECS 2000
Chemical structure		Howard and Meylan, 1997
Identification numbers: CAS Registry Number NIOSH RTECS EPA hazardous waste OHM/TADS DOT/UN/NA/IMCO shipping HSDB NCI	 117-81-7 TI0350000 U028 7216693 No data 334 C52733	 Cadogan and Howick, 1996 RTECS 2000 HSDB 1990 HSDB 1990 HSDB 1990 Montgomery and Welkom, 1990

CAS = Chemical Abstracts Services
DOT/UN/NA/IMCO = Department of Transportation/United Nations/North America/International Maritime Dangerous Goods Code
EPA = Environmental Protection Agency
HSDB = Hazardous Substances Data Bank
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
OHM/TADS = Oil and Hazardous Materials/Technical Assistance Data System
RTECS = Registry of Toxic Effects of Chemical Substances