

How medical devices are approved in Canada

In Canada, the system of approval for medical devices is governed by the *Medical Device Regulations* of the Department of Justice (<http://laws.justice.gc.ca/eng/SOR-98-282/20091229/>). Devices are classified into one of four categories according to risk. The criteria for classification are based on:

- the degree of invasiveness, the length of invasiveness, and the body system exposed to the device
- whether the device relies on a source of energy
- whether the device diagnoses or is therapeutic
- whether or not the device delivers energy to the patient (e.g., the device emits radiation)

The four classes are very similar to the four classes of devices in the EU.

Manufacturers of medical devices are also required to obtain an establishment licence from Health Canada. This licence contains an attestation from the manufacturer that it has put in place appropriate recall, problem-solving and complaint-handling procedures and that proper distribution records are maintained.

On its website, Health Canada maintains a list of all approved medical devices. For more details, visit <http://webprod.hc-sc.gc.ca/mdll-limh/index-eng.jsp>.

All manufacturers must ensure that their products comply with safety and effectiveness requirements as set out in the *Regulations* (sections 10 to 20).

Medical device classification

Medical devices are classified according to a number of rules. The rules can be grouped into four sets:

- invasive devices
- non-invasive devices
- active devices
- special rules

If a device can be categorized under more than one rule, the classification of highest risk applies. Exhibit 1 (below) lists the various submission requirements for each device classification. Class I devices are exempt from device-licensing requirements, but class II, III and IV devices require a medical-device licence from Health Canada prior to being imported, sold or advertised for sale.

Class I devices: These are not subject to any regulatory review. Manufacturers are required to obtain an establishment licence if they import or distribute through an entity that does not already hold a licence. The manufacturer is required to confirm that the facility has documented procedures for the distribution of records, as well as the handling of complaints and product recalls. Examples of class I devices include laboratory culture media and some surgical instruments.

Class II devices: A senior official of the manufacturer must attest to having objective evidence that the device meets safety and effectiveness requirements. Examples of class II devices include surgically invasive devices such as arterial or urethral catheters, dentures, contact lenses, home pregnancy tests, autologous blood reinfusion bags, and devices that penetrate the body such as syringe needles.

Class III devices: The manufacturer must submit a summary of all studies on which it relies to ensure the device meets safety and effectiveness requirements. Examples of class III devices include surgically invasive devices that are absorbed by the body or remain in the body for at least 30 days such as an implantable coronary stent, mammography X-ray systems or PSA tests.

Class IV devices: The manufacturer must provide detailed information on all studies on which it relies to ensure the device meets safety and effectiveness requirements, including pre-clinical and clinical studies, process validation studies, software validation studies (if appropriate), and literature studies. The manufacturer must also provide a summary of all these studies. Examples of class IV devices include breast implants, prosthetic heart valves, and HIV test kits.

Exhibit 1: Canadian medical device submission requirements

Submission requirements	Class			
	I	II	III	IV
Name of device	X	X	X	X
Class of device	X	X	X	X
Device identifier	X	X	X	X
Name and address of manufacturer	X	X	X	X
Name and address of place of manufacture	X	X	X	X
Description of conditions, purposes and uses for which device is sold		X		
List of standards complied with to satisfy safety and effectiveness requirements		X		
Attestation that manufacturer has objective evidence to establish that device meets safety and effectiveness requirements		X		
Attestation by manufacturer that label meets applicable requirements		X		
For <i>in vitro</i> diagnostics, attestation that investigational testing has been done on human subjects representative of intended users and under conditions similar to conditions of use		X		
Copy of quality management certificate certifying that quality management system satisfies ISO 13485:2003		X		
Description of device and materials used in its manufacture and packaging			X	X
Description of features of device			X	X
List of all countries other than Canada where it has been sold, number of units sold, and summary of any reported problems or recalls			X	X
List of standards complied with in design and manufacture to satisfy safety and effectiveness requirements			X	X
For sterile devices, description of sterilization method			X	
Summary of all studies relied on by manufacturer to ensure safety and effectiveness and conclusions drawn by manufacturer			X	X
Copy of device label			X	X
For a near-patient <i>in vitro</i> diagnostic device, summary of investigational testing using human subjects representative of intended users and under conditions similar to conditions of use			X	X
Bibliography of all published reports dealing with use, safety and effectiveness of device			X	X
Copy of quality management certificate certifying that quality management system satisfies ISO 13485:2003			X	X
Risk assessment comprising an analysis and evaluation of risks, and the risk reduction measures adopted to satisfy the safety and effectiveness requirements				X
Quality plan setting out the specific quality practices, resources and sequence of activities relevant to the device				X
Specification of materials used in the manufacture and packaging of the device				X
Manufacturing process				X
Detailed information on all studies on which manufacturer relies to ensure device meets safety and effectiveness requirements including pre-clinical and clinical studies, process validation studies, software validation studies (if appropriate), and literature studies.				X

For devices, other than <i>in vitro</i> diagnostic, incorporating animal or human tissue, objective evidence of biological safety	X
For a near-patient <i>in vitro</i> diagnostic device, detailed information on investigational testing using human subjects representative of intended users and under conditions similar to conditions of use	X

Source: Department of Justice, *Medical Device Regulations* (SOR/98-282), <http://laws.justice.gc.ca/eng/regulations/SQR-98-282/>

Medical devices for investigational testing

Class I devices do not need approval from Health Canada for investigational testing as long as the required documentation and records are kept. An application for investigational testing must be sent to Health Canada for class II, III and IV devices. The type of information to be submitted varies depending on the classification of the device. Class II device investigational applications should identify the manufacturer, the device, the name of the institution where the testing will occur, the testing protocol and a sample of the device label. Class III and IV investigational applications should contain additional information on risk analysis, the device's design philosophy and performance specifications, information on previous studies with the device, and its marketing history.

All clinical studies for unapproved class II, III and IV medical devices must also receive approval from an independent Research Ethics Board as well as Health Canada and must be conducted according to the *Good Clinical Practice* guidelines. Details on what is required can be found in the Therapeutic Products Directorate guideline, *Preparation of an Application for Investigational Testing - Medical Devices*, February 22, 1999 (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/test_md3_im3-eng.php#il).

Quality system requirements

Manufacturers of class II, III and IV devices are required to adhere to ISO 13485:2003 *Medical devices-Quality management systems -Requirements for regulatory purposes*. Manufacturers of class II devices do not have to adhere to the requirements related to design, but class III and IV manufacturers must adhere to all ISO 13485:2003 requirements.

As part of the application for a medical device license, a manufacturer must submit certification that it has been audited by a third party that has been accredited by the Standards Council of Canada and recognized by the Canadian Medical Devices Conformity Assessment Scope (CMDCAS).

Documentation and safety reporting

Manufacturers are required to maintain distribution records with respect to each medical device as well as records that relate to complaints or any reported problems regarding the performance characteristics or safety of a device.

The manufacturer is required to submit information to Health Canada regarding any

- failure of the device
 - deterioration in its effectiveness
- OR
- inadequacy of labelling or in directions for use

that results in the death or serious health deterioration of a patient, user or other person, or that could do so should the incident recur.

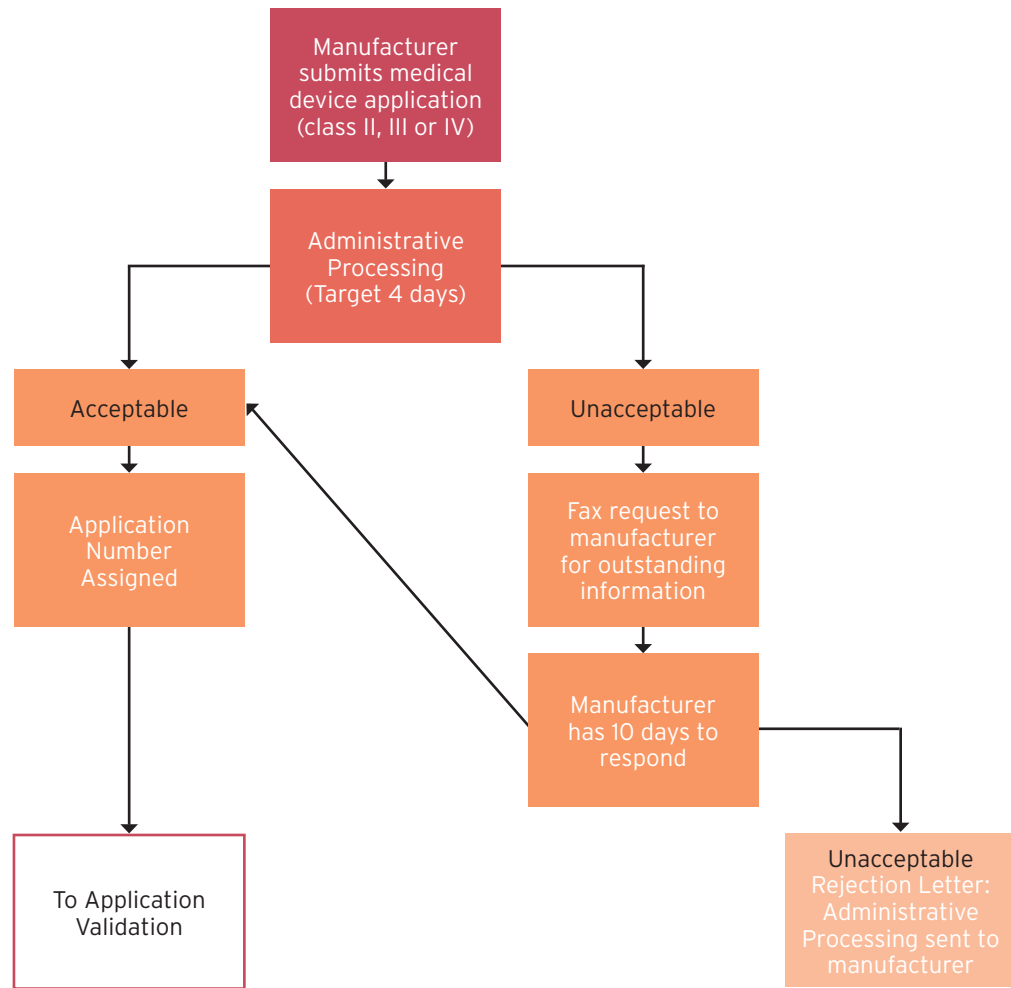
Health Canada has a standard form for the reporting of medical device problems (FRM-0029: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep_md_prob-rap_inc_im-eng.php).

For an event that occurs in Canada, the information must be submitted within 10 days after the manufacturer becomes aware of the incident if it results in death or serious deterioration in health. For events that have not led to death or a serious deterioration in health, but could do so should the event recur, the manufacturer has 30 days to report the incident to Health Canada. For an incident that occurs outside Canada, the manufacturer must report the information to Health Canada as soon as possible after the manufacturer has indicated to the appropriate regulatory agency the corrective action that it intends to take.

Medical device approval process

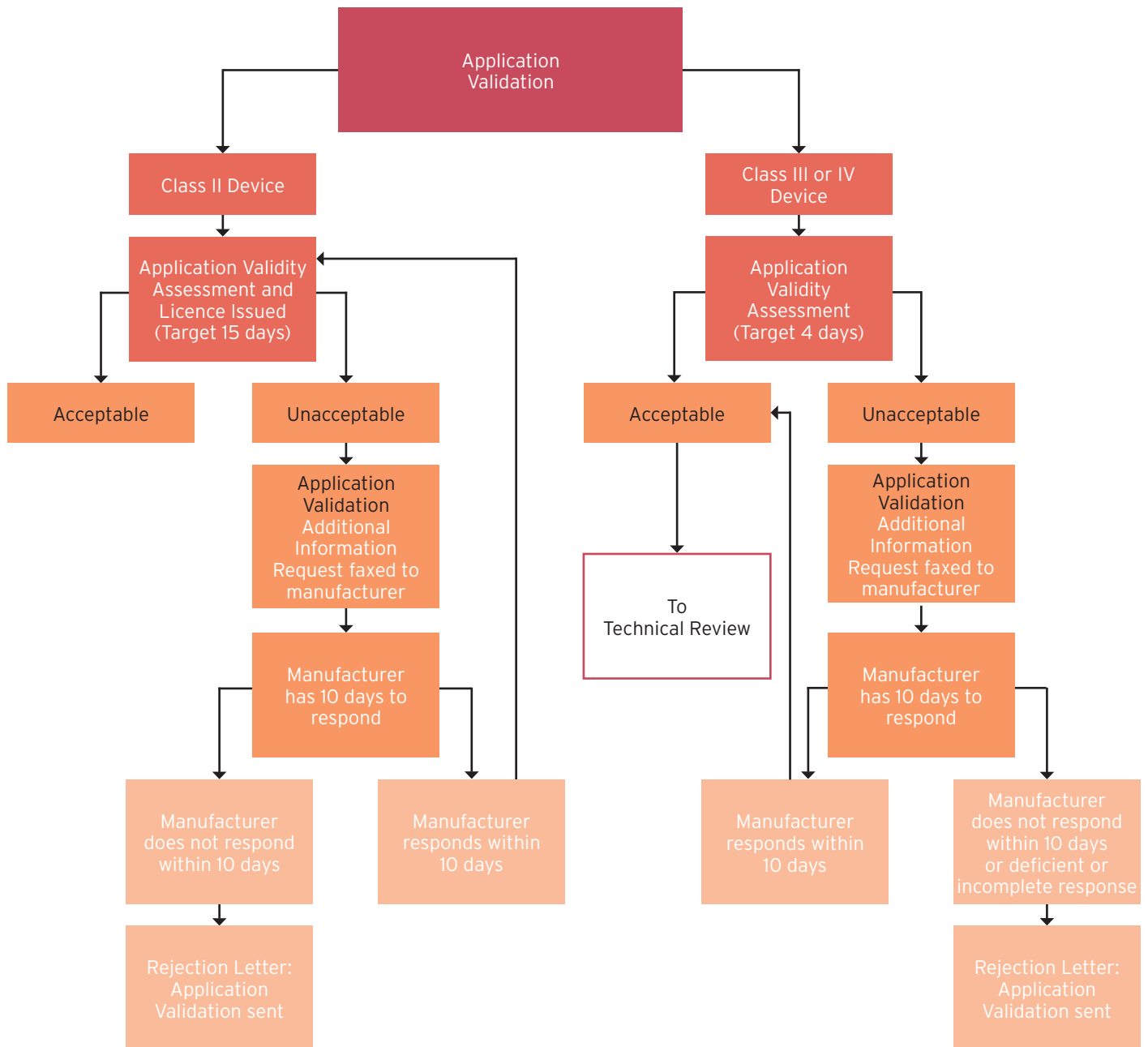
All class II, III and IV medical device applications are submitted to the Medical Devices Bureau at the Therapeutics Products Directorate of Health Canada. They undergo an administrative review, application validation and a technical review (if class III or IV). Exhibits 2, 3 and 4 illustrate the process involved at each stage of review.

Exhibit 2: Administrative process for class II, III or IV device applications



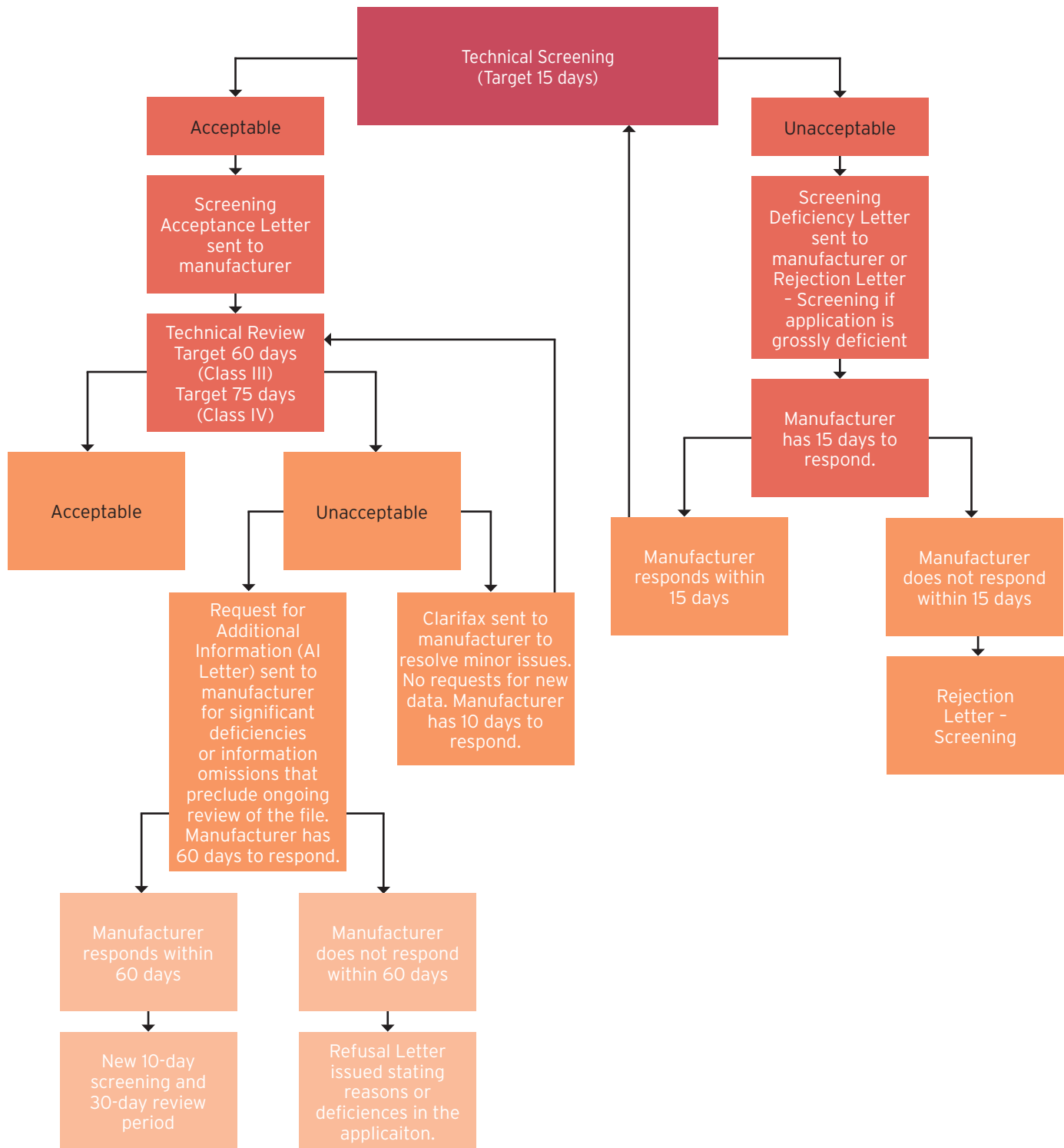
Source: Adapted from *Management of Applications for Medical Device Licenses and Investigational Testing Authorizations*. Therapeutic Products Directorate, Health Canada.

Exhibit 3: Application validation process for class II, III or IV device applications



Source: Adapted from *Management of Applications for Medical Device Licenses and Investigational Testing Authorizations*. Therapeutic Products Directorate, Health Canada.

Exhibit 4: Technical review process for class III or IV device applications



Source: Adapted from *Management of Applications for Medical Device Licenses and Investigational Testing Authorizations*. Therapeutic Products Directorate, Health Canada.