Guidance on summary reports and issue-related analyses for medical devices

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Publication date: April 2026

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Cat.: H164-309/2026E-PDF
ISBN: 978-0-660-98889-4
Pub.: 250497

Foreword

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. 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, effectiveness or quality of a therapeutic product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the relevant sections of the regulations and other applicable guidance documents.

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Overview

About the regulation of medical devices in Canada

The *Medical Devices Regulations* were established under the authority of the *Food and Drugs Act.* They set out the requirements for selling, importing and advertising medical devices in Canada.

Both Health Canada and regulatory agencies in other countries use a lifecycle approach to regulate medical devices. This approach involves evaluating the safety and effectiveness of a medical device (how well they work) before and after a product is authorized for sale in Canada. It recognizes that new information about the safety and effectiveness of a device can be learned once it's used:

- by the general public
- in a variety of situations, or
- for longer periods of time

Purpose of the guidance document

This guidance document was prepared to help medical device manufacturers understand and comply with sections 25, 39, 61.4 to 61.6 and 68.31 to 68.33 of the *Medical Devices Regulations* (regulations). Two requirements in the regulations were added to ensure the continued monitoring of benefits and risks after a product is authorized for sale in Canada. The 2 requirements concern:

- the preparation, retention and submission of summary reports (sections 61.4 to 61.6 and 68.31 to 68.33 of the regulations)
- the completion of issue-related analyses of safety and effectiveness (subsection 25(1) and sections 39 and 68.23 of the regulations)

This guidance document:

- clarifies Health Canada's expectations for the preparation of these summary reports and issue-related analyses

- gives an overview of the requirements and procedures for submitting summary reports and issue-related analyses to Health Canada

A **summary report** is a comprehensive assessment of **new** information on the benefits and risks of a licensed Class II, III or IV medical device or a Class II, III or IV medical device authorized under Part 1.1 of the regulations. The summary report regulatory requirement **does not** apply to Class I devices.

Medical device licence holders and holders of an authorization under Part 1.1 of Class II, III and IV devices are required to complete summary reports at periodic intervals. This requirement is outlined in sections 61.4 and 61.5 and 68.31 and 68.32 of the regulations.

If it's believed that a medical device authorized for sale in Canada may not meet safety and effectiveness requirements, Health Canada may also ask manufacturers of a Class I, II, III or IV medical device to prepare and submit an **issue-related analysis**. This authority is specified in sections 25 and 39 of the regulations. Used as an information-gathering tool, these types of requests help us determine whether devices still meet the safety and effectiveness requirements. Requests by Health Canada for more information or an analysis:

- usually concern a new or increased potential risk related to the use of a device in Canada
- allow Health Canada to make informed decisions about the need for risk management in relation to the potential risk

Summary reports and issue-related analyses help identify changes to what's known about the benefits and risks of medical devices used in Canada. We can then decide on the necessary action to help protect the health and safety of Canadians.

Scope and application

Medical device licence holders and holders of an authorization under Part 1.1 must comply with the applicable summary report provisions under sections 61.4 to 61.6 or sections 68.31 to 68.33 of the regulations. Manufacturers must comply with the issue-related analysis of safety and effectiveness provisions under subsection 25(1) and sections 39 and 68.23 of the regulations.

These requirements also apply to private label manufacturers. For more information on these requirements, see Health Canada's policy on private label manufacturers. Under their own name, private label manufacturers may sell a medical device produced by

another manufacturer who holds the licence for that device, when certain conditions are met.

However, like other regulated requirements, the original manufacturer may perform many of the activities involved in this guidance, if appropriate. To comply with the requirements, a private label manufacturer should establish processes to ensure timely and effective communication with the manufacturer and ensure that they remain compliant with the regulations.

Policy objective

These regulatory requirements are intended to implement a lifecycle approach to the regulation of medical devices in Canada. Strengthening monitoring after a device is authorized for sale in Canada helps to ensure that requirements related to safety and effectiveness continue to be met.

Summary reports

About summary reports

This guidance document was prepared to help medical device manufacturers understand and comply with the *Medical Devices Regulations* (regulations). Two new requirements in the regulations were added to ensure the continued monitoring of risks after a product is authorized for sale in Canada. The 2 requirements concern:

- the preparation, retention and submission of summary reports (sections 61.4 to 61.6 and 68.31 to 68.33 of the regulations)
- the completion of issue-related analyses of safety and effectiveness (subsection 25(1) and section 39 of the regulations)

Unless specified, for the purpose of this document, holder refers to:

- A holder of a Class II, III, or IV medical device licence, and
- A holder of an authorization

Unless specified, for the purpose of this document, authorization refers to:

- an authorization issued under section 68.12 of the regulations for a Class II to IV medical device that is not an urgent public health need (UPHN) medical device

For summary reports, holders must conduct a concise, critical analysis periodically from information received about the use of their licensed or authorized device(s). This information comes from reports of:

- adverse effects
- problems reported to the manufacturer, importer or distributor of the device relating to performance characteristics or safety, including any consumer complaints
- incidents that have come to the attention of the manufacturer or the importer of the device (sections 59(1) and 68.27 of the regulations)
- serious risks of injury to human health that were identified outside of Canada (subsection 61.2(2) and section 68.3 of the regulations)

Holders must then prepare a report that summarizes the relevant information received during the reporting period.

When preparing the summary report, the holder must determine if there has been a change in what's known about the benefits and/or risks associated with the device. If the holder determines that there has been a change, they must notify Health Canada in writing within 72 hours. Further details on how to notify Health Canada are included below.

All of the information in a summary report belongs to ongoing post-market monitoring by holders. The timing, frequency and type of scanning should depend on a number of factors, such as:

- the risk profile of the device, with details of the risks and benefits
- any known or specific issues that have arisen
- the scheduling of the summary report

Identified and potential safety issues, as well as knowledge gaps (for example, related to new patterns of use or long-term use), may require more active monitoring.

Health Canada may ask for a summary report and/or the information used to prepare the report if an examination of the benefits and/or risks of the device is determined to be necessary. We may request this at any time.

This information should increase knowledge about the benefits and risks associated with the use of a device in real-world situations.

Timelines for preparing summary reports

Summary reports must be prepared as follows:

- for Class II devices: every 2 years with information gathered during the previous 24 months
- for Class III and IV devices: every year with information gathered during the previous 12 months

The reporting period isn't tied to the anniversary date of a medical device licence or authorization. Holders may choose the reporting period for the report as long as the report falls within the required reporting timeframe. With this flexibility, holders are able to use the

same timeline for both the Canadian summary report and similar reports created to meet the requirements of international jurisdictions.

Holders are required to prepare summary reports for as long as their device is licensed or authorized in Canada.

How devices are grouped

A summary report is required for each medical device licence or authorization.

It may be reasonable to combine certain devices when preparing a summary report, even if they're not included in the same licence or authorization. Combining devices can help to identify changes to what's known about the benefits or risks of those devices. For example, how devices are used may reveal risks that are harder to find when information relevant to only one licence is assessed in isolation.

Devices can be grouped into 1 of 4 types as defined in the regulations:

1. medical device family
2. medical device group
3. medical device group family or
4. medical device system

Note: When grouping devices in accordance with a medical device system, it is not necessary that all of the components or parts be sold under a single name.

As holders are the most knowledgeable about their own devices, they're in the best position to determine how to combine devices when preparing a summary report. Holders are responsible for grouping in a way that's best for identifying changes to what's known about the benefits or risks of their device(s). A decision to group devices or combine data should not prevent issues from being identified that would have been detected without the grouping.

If a holder decides to combine devices that are not included under a single licence or authorization, they should provide a rationale to support their decision. Grouping devices just because they're manufactured in the same manufacturing facility and have the same users, cautions or intended use may not be an acceptable rationale. The rationale should explain how the grouping does not prevent the ability of the licensee to analyze data or detect changes to what's known about the benefits or risks of each device.

Devices can also be grouped in a manner that has been specified in jurisdictions outside Canada to meet similar periodic reporting requirements. It's possible to use the same grouping combination to meet Canada's regulatory requirements, however, this must meet Health Canada's summary reporting requirements.

Acceptable format and information to include

The summary report should add to the cumulative knowledge about the safety and effectiveness of a device from real-world use. The depth of analysis required for the report depends on the nature and amount of information collected. More information and greater analysis may be required for higher-risk devices.

The report should summarize and integrate new cumulative safety and effectiveness knowledge gained from experience during the reporting period. While it may be prepared as a cumulative summary from the date of first licensing, authorization or sale in Canada, conclusions should be specific to the reporting period.

Information specific to the Canadian context is an important part of the summary report. Canadian adverse effects, problems and incidents must be included in the analysis, if applicable. Including information about the use of the device outside Canada is also recommended. Such information gives a more fulsome view of the device's risks and benefits.

Different formats are acceptable for a summary report, including those from other jurisdictions, as long as the report includes the required information outlined in subsections 61.4(1) to 61.4(5) or subsections 68.31(1) to 68.31(5) of the regulations.

For example, the Periodic Safety Update Report format as required in the European Union may be an acceptable approach to fulfilling the summary report requirement in Canada.

Information in a summary report may vary from report to report. However, a report should contain the following sections:

- introduction or cover page
- summary of changes to the device, licence or authorization
- analysis
- conclusion

Be sure to provide an explanation if a particular section is not completed (for example, no new information).

Introduction or cover page

Identify the licence(s), authorization(s) and device(s) covered under the summary report and include:

- date of the report
- time period for which the report is being completed
- device licence or authorization number and details on the medical device, medical device group, medical device family and/or medical device group family
- identifier(s), if applicable
- name and address of the holder
- list of countries where the device(s) was/were distributed, sold or available during the reporting period

Summary of changes to the device, licence or authorization

In this section of the report, you should provide a summary of changes to the device, the licence or authorization in Canada since the last summary report, including:

- changes made to the device or its labelling that relate to benefits or risks of the device (for example, design, intended use, contraindications)
- applications made to Health Canada for a licence or authorization amendment under sections 34 and 68.13 of the regulations concerning benefits or risks of the device
- recalls issued in and outside of Canada if they pertain to a serious risk of injury to human health
- changes to the information and documents supplied by the manufacturer with respect to the device, as required by paragraph 43(1)(b) and section 68.34 of the regulations

You may reference information already documented in your quality management system records. However, this information should be easily retrievable in case Health Canada has further questions.

Analysis

As identified in subsections 61.4(3) and 68.31(3) of the regulations, you must consider the following elements when preparing the critical analysis:

- possible adverse effects associated with using the medical device
- problems related to performance or safety, including any complaints received by the manufacturer, importer or distributor after the device was first sold in Canada (paragraph 57(1)(a) of the regulations)
- incidents concerning a device's failure, deterioration in effectiveness, inadequate labelling or directions for use that have led to a person's death or serious deterioration in health, or could do so if the incident occurred again (subsection 59(1) of the regulations)
- serious risks of injury to health that are relevant to the safety of the device (subsections 61.2(2) and 68.3 of the regulations)
- misuse or off-label use of the medical device resulting in changes to what is known about benefits or risks associated with the device

As a holder, you should consider the above information in light of the number of devices sold or of estimated patient exposure to help assess the risk. For example, include Canadian sales rates if they're available. You could also use sales rates in other countries where the device is marketed to help with your analysis.

You should also consider whether the number of units sold reflects exposure most accurately. For example, using units sold would only be valid for single-use devices. For other devices, it may be better to consider the number of procedures performed or patient hours using the device. For example, for devices that are used multiple times, such as infusion pumps or glucose monitors, it may be more appropriate to estimate the number of uses overall or patient hours using the device. You should also consider breaking out data based on indicated use or patient population.

Data gathered for analysis should also include data collected outside of Canada if there is limited Canadian data.

If available, include the following types of evidence in the analysis:

- clinical evidence updates (any new relevant clinical data from published sources, device-related investigations or ongoing clinical studies)

- information on safety or effectiveness (including published reports)
- product- or issue-specific information
- information on similar devices, including those using similar materials and/or technology

You may include other information that would be helpful to understand the risks and benefits of a device.

Conclusion

The conclusion should provide:

- an overall assessment of the benefits and risks of your device, including a determination of whether a change to the benefits or risks has occurred during the reporting period
- any changes to the benefits or risks that were identified
- any preventive or corrective actions that have been considered or implemented or that are planned as a result of the identified change

As specified in subsections 61.4(4) and 68.31(4) of the regulations, the holder shall determine whether there has been a change to what's known about the benefits and risks associated with the medical device. This change could include any of the following:

- the potential benefits for patients through the use of the medical device may be less
- in respect of each of the risks:
  - the harm associated with the risk is more likely to occur or
  - if the harm associated with the risk occurs, the consequences for the health or safety of patients, users or other persons could be more serious
- a new risk has been identified

For the purposes of this guidance document, a "**change**" has occurred when it's believed the device may no longer meet the applicable requirements (sections 10 to 20 of the regulations). This belief should be based on the critical analysis that was completed as part of the summary report (subsections 61.4(3) and 68.31(3) of the regulations).

Here are 3 examples of a change.

1. The regulatory requirements related to safety and effectiveness were met at the time of authorization for a Class III device that is meant to remain in the body throughout its projected useful life of 10 years. While completing a summary report, it was found that a previously recognized adverse effect related to the device is occurring more often than expected after 5 years. The device's benefits haven't changed. Based on this new information, there is reason to believe that section 10 of the regulations may no longer be met. This shows that the harm associated with this risk is more likely to occur.
2. The regulatory requirements related to safety and effectiveness were met at the time of authorization for a reusable, Class II home-use device. The device is being used according to the instructions and within its projected useful life. While completing a summary report, it was found that the device's performance is deteriorating sooner than anticipated. As a result, the safety of patients is negatively affected. Based on this new information, there is a reason to believe that section 13 of the regulations may no longer be met. This presents a new potential risk.
3. The regulatory requirements related to safety and effectiveness were met at the time of authorization for a Class IV implant. The device is known to have many potential risks, including death, but the benefits outweighed the risks. While completing a summary report, it was found that the benefits of the device are less than expected with use in a real-world situation. Based on this new information, there is a reason to believe that section 11 of the regulations may no longer be met. This presents a decrease in the benefits that may be obtained by patients.

Potential corrective actions concerning the identified change to benefits or risks could be considered as having been met by:

- implementing a recall
- applying for a medical device licence or authorization amendment as a result of a change described in sections 34 or 68.13 of the regulations

In the conclusion, you should clearly state if, while completing the summary report, you determined that there was no change to the benefits and/or risks of the device.

Notifying Health Canada of a change in benefits or risks

If you determined that there was no change to the benefits and risks of your medical device since the previous reporting period, you do **not** need to submit the summary report to Health Canada.

As specified in subsections 61.4(6) and 68.31(6) of the regulations, the holder must notify Health Canada in writing within 72 hours after concluding that there has been a change to what's known about the device's benefits and risks.

Methods to notify Health Canada include:

- submission of an **application for a medical device licence or authorization amendment** under sections 34 or 68.13 of the regulations, such that the amendment addresses the identified change
    - for Class III to IV devices, for example, refer to the guidance for the interpretation of a significant change of a medical device
- notification of a **recall** of the impacted device(s) as outlined in sections 63 to 65 of the regulations, such that the recall addresses the identified change
    - refer to the guide to recalling medical devices
- submission of the **summary report**

If your submission of the summary report is your way of notifying Health Canada about the identified change to the benefits and/or risks of a device, you must include in the notification:

- a cover letter indicating that the information is being sent to fulfill the summary report requirements and clearly identifying the significant change, as outlined in subsections 61.4(6) and 68.31(6) of the regulations
- the most recently completed summary report

In many cases, the holder will have identified a change to the benefits and/or risks of a device through the course of ongoing monitoring activities. As a result, the holder may have implemented preventive or corrective actions and notified Health Canada during the reporting period (before completing the summary report). If this is the case, the holder must document in the summary report that:

- any necessary preventive or corrective actions were already taken in relation to the identified change to the benefits and/or risks of the device
- Health Canada has already been notified (through a recall notification or submission of a licence or authorization amendment application, for example)

Note: Unless requested, do **not** submit the summary report if you have already notified Health Canada about a change you identified while completing the report. As specified above, this prior notification may have occurred through compliance with other regulatory requirements.

The notice and related documents must be submitted in either English or French.

To submit a summary report to us:

devicelicensing-homologationinstruments@hc-sc.gc.ca

For questions about which changes in risks and benefits require notification, contact the Medical Devices Directorate at:

devicelicensing-homologationinstruments@hc-sc.gc.ca

Requests for summary reports or supporting information

To determine whether a medical device still meets safety and effectiveness requirements after approval, the Minister may request one or more of the summary reports from the holder. The Minister may also ask for the information used to create them. The request may be made at any time. The Minister may set a date when the summary reports must be submitted to Health Canada.

Retention time for keeping summary reports

As a holder, you must keep for 7 years:

- copies of your summary reports and
- the information used to prepare the reports

The reports and supporting information must be maintained onsite or be easily accessible.

You should also keep data used to generate the reports for 7 years in case the statistical analyses need to be validated.

During inspections, Health Canada's inspectors may ask to see your summary reports.

Issue-related analyses of safety and effectiveness

Overview

This guidance document was prepared to help medical device manufacturers understand and comply with the *Medical Devices Regulations.* Two new requirements in the *Regulations* were added to ensure the continued monitoring of risks after a product is authorized for sale in Canada. The 2 requirements concern:

- the preparation, retention and submission of summary reports (sections 61.4 to 61.6)
- the completion of issue-related analyses of safety and effectiveness (sections 25(1) and 39)

With respect to issue-related analyses, Health Canada may request an analysis from a manufacturer of a Class I medical device or a licence holder of a Class II to IV medical device on a safety or effectiveness issue. This is outlined in sections 25 and 39 of the *Regulations*. We may make the request at any time. Along with other available information, we will use these analyses when assessing the safety and effectiveness of a device authorized for sale in Canada.

Health Canada conducts a post-market benefit/risk assessment when there's a reasonable belief that the benefits and/or risks of a medical device may have changed. We may identify a new or increased risk and/or a potential decrease in benefits concerning the use of a medical device by monitoring various sources of information, including:

- individual reports of incidents and other adverse effects
- scientific literature
- information exchanged between foreign regulators
- other sources of information about the experiences of patients

For Class I devices, the manufacturer is responsible for completing the analysis and submitting it to Health Canada.

For Class II to IV devices, the medical device licence holder is responsible for completing the analysis and submitting it to Health Canada.

Types of information to include in an issue-related safety and effectiveness analysis

An analysis should be concise and fulfill the requirements set out in the request issued by Health Canada.

Information in an issue-related safety and effectiveness analysis should contain the following sections:

- device complaints and incident reports
- clinical data and other evidence
- exposure data or sales data
- device malfunction trends, quality issues and results from other analyses
- labelling
- conclusion

Device complaints and incident reports

The manufacturer of a Class I device or the medical device licence holder of a Class II to IV medical device should consider information that relates to the specified issue, including:

- complaints as outlined in section 57(1)(a) of the *Regulations*
- incidents as outlined in 59(1) of the *Regulations*
- other data or evidence that is available to the authorization holder

Information specific to Canada is recommended. Conditions of use in Canada may differ from other countries due to differences in authorized indications or practice patterns. Conversely, Canadian-specific information can sometimes be limited for some devices. As a result, information about the use of the device outside Canada should be used when available and relevant.

Depending on the nature of the issue and the information considered necessary to inform decision-making, the Minister may also specify:

- the years for which device complaints and/or incidents should be included
- jurisdictions outside of Canada that are of interest

- the requirement to include patient outcomes
- the inclusion of non-serious adverse effects, including those that would not meet the definition of “incident” in the *Regulations*

Clinical data and other evidence

Include any clinical data and other evidence updates that relate to the specified issue, such as:

- new relevant clinical data from published sources or device-related investigations
- clinical study outcomes from completed or ongoing studies, which could include patient-specific outcomes
- pre-clinical safety data
- clinical studies to support claims
- pre-clinical test data and analysis to confirm safety
- other clinical results (for example, long-term follow-up studies)
- ongoing or completed post-market studies conducted by the manufacturer
- published scientific literature

Exposure data or sales data

Data related to the exposure of the medical device should be included, when relevant and available. Depending on the type of device, “exposure” data may vary. For single-use devices, using the number of units sold would be valid. For devices that are used multiple times, such as infusion pumps or glucose monitors, it would be more appropriate to estimate the number of procedures/uses, health care facilities impacted or patient hours using the device, for example.

When possible, exposure data can help to put into context the number of incidents reported (for example, reporting rates). A rationale should be provided if it’s not possible to calculate reporting rates.

Device malfunction trends, quality issues and results from other analyses

Include any information relating to device malfunction and quality issues. Examples may include root cause analysis, failure modes and effects analysis, and fault tree analysis.

Labelling

As part of the analysis related to the specified issue, you should consider whether the current labelling includes the information needed to use the device safely and effectively. Information related to any potential risks should also be assessed.

Regulatory requirements related to labelling are set out in sections 21 to 23 of the *Regulations*, with additional information provided in our guidance documents on:

- labelling medical devices, not including in vitro diagnostic devices
- labelling in vitro diagnostic devices

Briefly, depending on the product, labelling may include:

- information attached to the device
- package inserts
- brochures
- leaflets

Conclusion

It's important to present your conclusions about the identified issue. You may consider how the issue affects the overall safety and effectiveness of the device and whether mitigation strategies are needed to address any risk.

If you conclude that mitigation strategies are necessary, you should outline the strategies that you have taken or intend to take. You should also consider:

- actions taken or planned in response to problems reported (see paragraph 57(1)(b) of the *Regulations*)
- root causes identified and/or actions taken or planned as a result of the investigation of incidents (see section 61.2 of the *Regulations*)

Timeframe for submitting an analysis

The request for analysis will specify the timeframe in which the analysis should be submitted to the Minister. The default timeframe for submitting an analysis is 30 calendar days from the date of the request. However, the Minister may ask for the report in less than 30 calendar days if the information is needed to determine if the medical device poses a serious and imminent risk to human health.

You should provide the analysis to Health Canada in electronic-only format, in either English or French. Please send your analysis by email to devicelicensing-homologationinstruments@hc-sc.gc.ca with a cover letter. In your letter, include the licence number and the reason for the submission (for example, response to sections 25 or 39).

Compliance and enforcement

If Health Canada identifies instances of non-compliance, we may then take compliance and enforcement measures following the risk-based approach outlined in the compliance and enforcement policy for health products (POL-0001). If non-compliance isn't resolved, we may apply the provisions of the *Food and Drugs Act* and its associated regulations (outlined in the policy).

Should a manufacturer of a Class II to IV device fail to comply with a request for analysis, the Minister may suspend the licence.

Should a manufacturer of a Class I device fail to comply with a request for analysis, the Minister may direct the manufacturer to stop the sale of the medical device.