Ministry of Health and Long-Term Care

Personal Service Settings Guideline, 2018

Population and Public Health Division
Ministry of Health and Long-Term Care

Effective: July 1, 2018

Ontario

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1. Preamble

The Ontario Public Health Standards: Requirements for Programs, Services, and Accountability (OPHS) are published by the Minister of Health and Long-Term Care under the authority of section 7 of the *Health Protection and Promotion Act* (HPPA) to specify the mandatory health programs and services provided by boards of health.[1,2] The Standards identify the minimum expectations for public health programs and services. Boards of health are accountable for implementing the Standards including the Protocols and Guidelines that are referenced in the Standards. Guidelines are program and topic-specific documents which provide direction on how boards of health shall approach specific requirement(s) identified within the Standards.

2. Purpose

This guideline supports the implementation of the *Infection Prevention and Control Protocol, 2018* (or as current), the *Infection Prevention and Control Complaint Protocol, 2018* (or as current), and the *Infection Prevention and Control Disclosure Protocol, 2018* (or as current) of the Infectious and Communicable Diseases Prevention and Control Standard, under the OPHS.

Personal service settings that offer tanning bed services must also be in compliance with the *Skin Cancer Prevention Act (Tanning Beds), 2013* and the *Tanning Beds Compliance Protocol, 2018* (or as current).

This guideline is intended to assist Boards of Health (Boards), in implementing and interpreting the requirements of *Ontario Regulation 136/18 – Personal Service Settings* under the HPPA (Regulation), which came into force on July 1st, 2018. The guideline is not intended to stand alone, but rather to be used in conjunction with the regulation and establishes the minimum expectations for strategies and approaches for Boards.

The sections of this guideline outline the related requirements of the Regulation; however, not all sections of the Regulation will be covered. It is important to be familiar with all of the requirements of the Regulation.

Where there is a discrepancy between any Ontario legislation (including the Regulation) and the requirements of this guideline, the legislation prevails.

3. Reference to the Standards

This section identifies the standard and requirements to which this guideline relates.

Infectious and Communicable Diseases Prevention and Control

Requirement 18. The board of health shall receive reports of complaints regarding infection prevention and control practices and respond to and/or refer to appropriate

regulatory bodies, including regulatory colleges , in accordance with applicable provincial legislation and in accordance with the *Infection Prevention and Control Complaint Protocol, 2018* (or as current); the *Infection Prevention and Control Disclosure Protocol, 2018* (or as current); and the *Personal Service Settings Guideline, 2018* (or as current).

Requirement 19. The board of health shall inspect and evaluate infection prevention and control practices in personal service settings in accordance with the *Infection Prevention and Control Complaint Protocol, 2018* (or as current); the *Infection Prevention and Control Disclosure Protocol, 2018* (or as current); and the *Personal Service Settings Guideline, 2018* (or as current).

Requirement 20. The board of health shall inspect settings associated with risk of infectious diseases of public health significance in accordance with the *Healthy Environments and Climate Change Guideline, 2018* (or as current); the *Infection Prevention and Control Complaint Protocol, 2018* (or as current); the *Infection Prevention and Control Protocol, 2018* (or as current); and the *Personal Service Settings Guideline, 2018* (or as current).

4. Required Approaches

The following subsections are aligned with sections of the Regulation and are intended to assist Boards in the implementation of the Regulation.

4.1 Application

Section 2 of the Regulation

Section 2 of the Regulation clarifies that a premises of a personal service setting (PSS) may include a vehicle, convention, exhibition, fair, festival or trade show, and Section 2(2) sets out exemptions from the Regulation.

As per the *Infection Prevention and Control Protocol, 2018* (or as current), the Board shall inspect all PSS as defined in section 1(1) of the HPPA and in section 2 of the Regulation no less than once every 12 months to ensure adherence to IPAC principles and public safety.

In the event that an operator of a PSS (operator) travels to the homes of clients or provides any other services to clients through a mobile premises, the Board shall inspect a minimum of one of the following locations within its jurisdiction, which may also serve as the location provided in the notice by the operator: (1) where equipment is reprocessed or stored, (2) where the business head office is located, (3) where the vehicle is stored, or (4) where the operator resides. Should a mobile premises be multi-jurisdictional (e.g. offers services in one or more health units but has, for example, the business head office in another health unit), discussions between the respective health units may take place to coordinate inspections.

Section 2(2)(e) provides that personal services being provided at a client's dwelling (i.e. at the client's home) are not subject to the requirements of the Regulation.

Section 2(2)(b) and (c) provide that long-term care homes and retirement homes are exempt from the Regulation. However, if personal services are offered in these settings, Boards shall inspect these settings on a routine basis for potential health hazards and investigate should there be IPAC complaint that may result in the risk of infectious disease transmission between patients (please refer to the *Infection Prevention and Control Complaint Protocol, 2018* (or as current)).

Where a health hazard has been identified, a public health inspector (PHI) or Medical Officer of Health (MOH) should consider issuing a health hazard order under s. 13 of the HPPA, where warranted.

PSS where personal services are primarily provided by regulated health professionals who are engaged in the practice of their profession are not subject to the regulation. For example, a dermatologist providing cosmetic services within the scope of his/her profession at a clinic that would otherwise constitute a PSS, are not subject to the requirements of the Regulation. However, a dermatologist providing manicures and pedicures at a PSS would not be exempt from the Regulation.

Therefore, "medi-spas" should be inspected to determine whether the personal services are primarily being provided by a regulated health professional **who is engaged in the practice of their profession**.

4.2 Notice to Boards

Section 3 of Regulation

Every operator of a PSS must provide notice to the MOH at least 14 days before commencing operation. The notice must provide: (1) the name and location of the intended PSS, (2) the name and contact information of the person intending to operate the PSS, and (3) a list of the personal services that will be provided at the PSS.

Notification to the MOH that a PSS is intending to operate or intending to modify the scope of personal services being offered is required by section 3 of the Regulation. This increases the communication between Boards and operators, and provides the opportunity for operators to obtain resources and to ensure compliance with the regulations and address any public health and safety concerns prior to services being offered.

As specified in the Regulation, all PSS are required to notify the MOH in which the setting is located of the intent to operate a PSS, and the services offered, at least 14 days before commencing operation. This provision is to ensure Boards are aware of **all** PSS within its jurisdiction.

Should the PSS modify or change the personal services offered, the operators are required to notify the MOH at least 14 days before commencing operation. In addition,

should the personal service move physical locations (either permanently or temporarily), the operators are to notify the MOH.

MOHs and PHIs are not required to inspect settings once they have been notified, as this does not support the risk-based approach required in the Protocol and deploys inspectors unnecessarily to settings which may be low risk. The notification provisions allows MOHs to determine if an inspection is required based on the risks associated with the services conducted.

If warranted, the MOH or PHI may request and review floor plans from the operator or local building and zoning departments. If obtained, the MOH or PHI may review the floor plans to ensure adherence to the Regulation, particularly with respect to setting requirements in section 8 of the Regulation.

4.3 Disclosure

Section 4 of the Regulation

Every operator must ensure that the results of any inspections conducted by a PHI are posted in accordance with the PHI's request.

Public disclosure of inspection results increases transparency and raises awareness of the inspection results to the public. Disclosure has been shown to provide motivation for operators to comply with legal requirements.

Boards are required to post inspection results of PSS on their website as per the *Infection Prevention and Control Disclosure Protocol, 2018*. Onsite disclosure is not a requirement of the Regulation and may be done at the discretion of the PHI. Should the PHI require operators to display onsite inspection results, the specifics of what is posted at the premises may be adapted to meet the needs of the jurisdiction. Boards without a disclosure program may chose to use a generic onsite posting sign that will direct the public on how to access inspection results on the Board's website.

4.4 Obtaining client information

Section 5 of the Regulation

Before providing a personal service, the operator or the person providing the personal service must obtain the name and contact information of the person seeking the service.

Collecting client information is useful for trace-back purposes, which is crucial should there be an infection prevention and control lapse, and allows for a comprehensive investigation and swifter response to mitigate potential disease transmission.

Operators shall ensure the name and contact information of every client is obtained prior to providing any personal service, both invasive and non-invasive. If a person chooses not to provide their name and contact information, the operator must not provide the service. While non-invasive personal services are likely lower risk, there is

still a potential risk to clients for accidental exposure to blood or body fluids, and Boards shall reinforce this requirement to operators.

4.5 Providing information for invasive procedures

Section 6 of the Regulation

Before providing an invasive procedure, the operator or the person providing the procedure must provide the person seeking the procedure with an explanation of the procedure and any risks associated with the procedure.

The operator may choose to explain aftercare instructions to the person receiving the service as part of the explanation of the procedure and risks for invasive services. Educating the client on the risks and providing aftercare instructions decreases negative consequences of the procedure.

To ensure operators are complying with the requirements of section 6, MOHs and PHIs shall inspect documentation records referred to in section 14(1)(3)(iv).

4.6 Prohibited Services

Section 7 of the Regulation

This section prohibits certain services, including ear candling and coning, as well as fish pedicures.

The MOH or PHI shall ensure that ear candling/coning and any personal service involving live aquatic species (e.g., fish pedicures) are not sold or provided at the PSS.

Ear candles or cones have safety concerns, including the risk of burns, fires, and medical complications, and the sale or importation of ear candles or cones for medical reason is prohibited in Canada by Health Canada. The use of aquatic species in personal services increases the risk of infections, as aquatic species are not able to be disinfected or sterilized between clients; the tank water may contain a number of microorganisms and cannot be cleaned and disinfected between clients; and, some aquatic species have the ability to grow teeth and can draw blood.

It is important to note scleral tattooing or implantation of eye jewelry under the conjunctiva is also prohibited by section 18.1 of the HPPA.

4.7 Setting requirements

Section 8 of the Regulation

There are a number of setting requirements to ensure the premise is constructed and maintained in a manner that supports a sanitary environment.

- **Personal services in a dwelling**

If personal services are provided in part of a dwelling, it must not be a room or part of a room that is used as a dwelling. Screens, curtains, etc. to partition part of a room used as a dwelling (e.g. the dining room) are not permitted.

- **Ventilation**

Ventilation shall be maintained to ensure the elimination of fumes, vapours, mist, dust, etc., and may include local exhaust to remove nail dust and chemical vapours in addition to what is required as per the *Ontario Building Code*.

- **Sinks**

A hand washing sink that is “accessible at all times” implies that there is a sink available and not that it is continuously accessible; therefore, a hand washing sink in a bathroom is permitted. It may be possible to repurpose an existing or extra sink and designate it as a hand washing sink or reprocessing sink, provided the requirements of the Regulation are being met.

Reprocessing areas shall be in an area away from where personal services are offered. The reprocessing area shall allow for one-way work flow of contaminated items properly through the reprocessing steps, which means there shall be separate areas for clean and used equipment, and that reprocessing flows from dirty to clean.

A two-compartment sink is not permitted as both a hand washing sink and a sink for reprocessing of reusable equipment. A two-compartment sink is ideal as a reprocessing sink.

Portable or temporary sinks are not permitted where it is used as a sink for the purpose of reprocessing reusable equipment.

- **Waste receptacles**

Biomedical waste shall be placed in an impervious bag or receptacle (e.g., sharps container), labelled as biomedical waste, and disposed of in a biohazard bag or container according to provincial legislation, biomedical waste guidelines and any applicable municipal by-laws. A locked, refrigerated space (at or below 4°C) shall be provided for storage of biomedical waste, excluding sharps, if stored for more than four days.

Packaging of biomedical waste for off-site disposal shall comply with the *Transportation of Dangerous Goods* regulations.

4.8 Animals

Section 9 of the Regulation

Animals, including birds, aquatic species, and reptiles, are not permitted in the PSS, except service animals as referenced in the relevant sections of the regulations under

the *Accessibility for Ontarians with Disabilities Act, 2005* (AODA) and live aquatic species displayed or stored in sanitary tanks. MOHs or PHIs do not need to verify that the animal is a service animal, unless it is not readily identified.

If a PSS is part of a dwelling (e.g., basement of the operators home), animals are not permitted in the room(s) that is serving as the PSS, unless an applicable exemption applies in the case of a service animal.

4.9 Equipment

Section 10 of the Regulation

This section has various requirements relating to equipment in a PSS. A few matters to note:

▪ Manufacturer's instructions

Electronic copies of manufacturer's instructions are acceptable provided they are accessible to every person providing a personal service or using the equipment.

▪ Protective covers

Protective covers can reduce the frequency of cleaning required for specific surfaces. If equipment is covered with a protective cover, the protective cover must be changed between clients, and care must be taken to avoid the contamination of surfaces when removing or changing the cover. If the surface becomes visibly soiled or contaminated, the surface shall be cleaned and disinfected. The covered surface must be uncovered and then cleaned and disinfected with a low-level disinfectant at the end of each day.

▪ Sharps containers

Sharps containers are biohazard containers and must not go into the regular garbage. In addition or as part of legislation requirements or Canadian Standards, sharps containers shall:

- Be clearly identifiable with a biological hazard label and designed so that used sharps may be dropped in with one hand;
- Be easily accessible at every point of use;
- Not be filled with disinfectant or over-filled with sharps; and
- Be sealed and replaced when the contents reach the filled line marked on the container or when three-quarters full.

For more information, refer to The Management of Biomedical Waste in Ontario and Canadian Standards Association standard Z316.6-14.[3,4]

▪ Sterilizers

Sterilizers are medical devices regulated by Health Canada. When purchasing a sterilizer, operators shall choose those that are licensed for sale by Health Canada by checking the Medical Devices Active License Listing.[5] Applicable standards established

by Health Canada and the Canadian Standards Association can be found in Appendix A.

The sterilization process shall be monitored to ensure the process in effective. Monitoring includes the use of mechanical or physical indicators, biological indicators, and chemical indicators.

Mechanical or physical indicators shall consist of: the length of time that the sterilization temperature was maintained; the temperature during sterilization; and, the pressure reached and maintained during sterilization.

Biological indicators shall be performed for analysis and for determination of whether the sterilization pass or failed and are promptly submitted to a laboratory capable of performing biological indicator testing and certified to industry standards.

An internal chemical indicator shall be placed inside each package, container, or bundle undergoing sterilization.

When a chemical indicator fails to change colour, mechanical monitoring shows suboptimal sterilization time or temperature, or moisture is observed in or on packages after sterilization, the equipment in that load shall not be used.

If the operator receives a report from a laboratory indicating that a sterilizer has failed/ positive biological indicator, the operator shall take necessary actions to address the cause and consequences of the failure; and, immediately inform the Board in which the setting is located of the failure. Boards may require operators to notify the Board of any sterilizer failures/positive BI under section 10(10)(a).

To verify the sterilizer is functioning correctly, operators shall run tests on the following occasions:

- Before putting a newly installed sterilizer to use
- After relocating a sterilizer
- After repairs that could affect the sterilizers performance
- Mechanical malfunctions of the sterilizer; and
- After power outages or other emergency scenarios

Unacceptable methods of sterilization include:

- Dishwashers
- Boiling
- Ultraviolet light or irradiation
- Glass bead sterilizers
- Microwave ovens
- Pressure cookers
- Flash sterilization
- Chemiclaves; and
- Glutaraldehyde

4.10 Products

Section 11 of the Regulation

A DIN or NPN number provides confidence with the effectiveness of the product and indicates that the product has undergone and passed a review of its strength, efficacy claims, and instructions for safe use. DIN and NPN's also assist in product recalls, inspections, and quality monitoring. Recently, Health Canada reclassified high-level disinfectants and sterilants as medical devices and will no longer carry a DIN. This policy is effective March 16, 2018 with an 18-month transition period.

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-classification-licensing-high-level-disinfectants-sterilants.html

For high-level disinfectants and sterilants, operators, MOHs and PHIs should consult the Medical Device Active License Listing (MDALL) to confirm if it is licensed with Health Canada.

Where manufacturer's instructions are not available for disinfectants (section 11(2)(b)), refer to Public Health Ontario's *Infection Prevention and Control in Personal Service Settings, 2018* (or as current).[6]

4.11 Hygiene

Section 12 of the Regulation

Hand hygiene is one of most important ways to stop the spread of infection. Using alcohol-based hand rub (ABHR) is appropriate when hands are not visible soiled and makes a more convenient option for workers at the point of service. To make it possible for personal service workers to clean their hands at the right time, ABHR must be available and within reach wherever personal services are provided and in reprocessing areas, even if a hand washing sink is available. This provision allows workers to choose between hand washing and using ABHR when their hands are not visibly soiled. Hand washing would still be required when hands are visibly soiled.

ABHRs shall:

- have an NPN or DIN from Health Canada, as per section 11(2) of the Regulation;
- not be used for surface or equipment disinfection; and
- not be installed over for directly adjacent to ignition sources or over carpeted areas.

Workers must wear gloves to protect their hands when it is anticipated that hands will be in contact with blood and/or other body fluids, non-intact skin, mucous membranes, contaminated equipment; and chemicals used in cleaning and reprocessing.

Reusable rubber gloves must be used only for reprocessing (cleaning, disinfection, or sterilization of equipment) or environmental cleaning. Reusable rubber gloves must be cleaned, disinfected, and hung to dry after each task.

4.12 Operator training

Section 13 of the Regulation

Every operator of a PSS must undertake and health and safety training if required by a MOH or PHI.

Training for operators is important because it ensures operators are aware of their responsibilities under the Regulation and are able to maintain the premises in a sanitary manner in order to recognize, prevent or reduce, and respond to the risks of disease transmission at the premises.

As a requirement of the *Infection Prevention and Control Protocol, 2018*, Boards are required the ensure education is provided to operators and their staff on appropriate IPAC practices.

The requirement for training in the Regulation does not specify a course or certificate; however, during an inspection, the PHI shall assess the knowledge of the operator in the operation and maintenance of the PSS, and any relevant practices that may prevent or reduce the risk of disease transmission. The MOH or PHI may require training or re-training of the operator, specifically if multiple regulatory infractions are noted, or the operator does not appear competent or knowledgeable in the regulatory requirements or in the safe operation of the premises.

Training may include on-site education from a public health inspector during an inspection, fact sheets, charts, posters, or directing operators to IPAC education sessions or courses.

Minimum competencies may include prevention of blood-borne infections; infection prevention practices specific to the services being provided; cleaning and disinfection of equipment; ability to follow manufacture or the Board’s instructions; and adherence to the regulatory requirements.

4.13 Records

Section 14 of the Regulation

Every operator of a PSS must keep records as specified in section 14 of the Regulation.

- **Sterilization records**

The MOH or PHI shall ensure the model and serial number of the sterilizer are documented, where available.

The MOH or PHI shall ensure monitoring records includes mechanical monitoring results as printouts from a sterilizer or a written log of parameters which will include date, sterilization temperature, pressure, and sterilization time.

There shall be a record kept by the operator of the equipment that was sterilized. The record is helpful for identification and holding, if necessary, and may include the use of lot numbers on equipment.

- **Disinfection records**

Disinfection records shall be maintained for high-level disinfectants.

5. References

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4. CSA Group. CAN/CSA-Z316.6-14: Sharps injury protection - Requirements and test methods - Sharps containers (Adopted ISO 23907:2012, first edition, 2012-09-01, with Canadian deviations). Toronto, ON: CSA Group; 2014.
5. Health Canada. Drug product database online query [Internet]. Ottawa, ON: Health Canada; 2015 [cited 2016 Aug 10]. Available from: https://health-products.canada.ca/dpd-bdpp/index-eng.jsp
6. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Infection prevention and in personal service settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2018

6. Appendix A

Z314.3-14 - Effective sterilization in health care settings by the steam process	Canadian Standards Association website: Z314.3-14
CAN/CSA-Z314.7-03 (R2013): Steam sterilizers for health care facilities	Canadian Standards Association website: Z314.7-03
CAN/CSA-Z314.13-01 (R2007) Recommended Standard Practices for Emergency (Flash) Sterilization	Standards Council of Canada, Z314.13-01 (this Council accredits the Canadian Standards Association)
CAN/CSA-Z314.9-09 (R2013) - Installation, ventilation, and safe use of ethylene oxide sterilizers in health care facilities	Canadian Standards Association website: Z314.9-09 (R2013)
CSA Z314.0:2013: Medical device reprocessing - general requirements	Canadian Standards Association website: Z314.0:2013
CSA Z314.8:2014: Decontamination of reusable medical devices	Canadian Standards Association website: Z314.8:2013
CSA SPE 1112-14: Medical device reprocessing in community health care settings	Canadian Standards Association website: 1112-14
CSA Z314.14-15: Selection and use of packaging (sterile barrier systems) in healthcare settings	Canadian Standards Association website: Z314.14-15
CSA Z314.23-16: Chemical sterilization of reusable medical devices in health care settings	Standards Council of Canada, CSA Z314.23-16
ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals ISO 10993-7:2008/Cor.1:2009	Health Canada – List of Recognized Standards for Medical Devices
ISO 13408-5:2006 Aseptic processing of health care products - Part 5 : Sterilization in place	Health Canada – List of Recognized Standards for Medical Devices
ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Health Canada – List of Recognized Standards for Medical Devices
CAN/CSA Z11135-1-09:2009 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Health Canada – List of Recognized Standards for Medical Devices
CAN/CSA Z17665-1-09:2009 Sterilization of health care products – Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	Health Canada – List of Recognized Standards for Medical Devices

ISO 11135-1:2007 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Health Canada – List of Recognized Standards for Medical Devices
ISO 11137-1:2006 Sterilization of health care products – Radiation – Part 1: Requirement for development, validation and routine control of a sterilization process for medical devices	Health Canada – List of Recognized Standards for Medical Devices
ISO 11137-2:2006 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose ISO 11137-2:2006/Cor.1:2009	Health Canada – List of Recognized Standards for Medical Devices
ISO 11137-3:2006 Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects	Health Canada – List of Recognized Standards for Medical Devices
ISO 11138-1:2006 Sterilization of health care products – Biological indicators – Part 1: General	Health Canada – List of Recognized Standards for Medical Devices
ISO 11138-2:2006 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes	Health Canada – List of Recognized Standards for Medical Devices
ISO 11138-3:2006 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes	Health Canada – List of Recognized Standards for Medical Devices
ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	Health Canada – List of Recognized Standards for Medical Devices
ISO 11607-2:2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	Health Canada – List of Recognized Standards for Medical Devices
ISO 11737-1:2006 Sterilization of medical devices – Microbiological methods – Part 1: Determination of population of microorganisms on products ISO 11737-1:2006/Cor.1:2007	Health Canada – List of Recognized Standards for Medical Devices
ISO 14937:2009 Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	Health Canada – List of Recognized Standards for Medical Devices
ISO 17664:2004 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices	Health Canada – List of Recognized Standards for Medical Devices

ISO 17665-1:2006 Sterilization of health care products – Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	Health Canada – List of Recognized Standards for Medical Devices
Guidance Document: Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices "Guidance documents have been prepared to assist in the interpretation of policies and governing statutes and regulations. They are intended to assist in preparing the various device licence applications required when seeking an authorization to sell a medical device product in Canada. Guidance documents are designed to be living documents and will be revised as necessary."	Health Canada > Drugs and Health products > Medical Devices > Application Information > Guidance Documents – Medical Devices

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