3D printing and other manufacturing of personal protective equipment in response to COVID-19

Background

During the COVID-19 pandemic, the demand for certain medical devices, including personal protective equipment (PPE), may exceed the available supply in Canada. Health Canada recognizes that organizations may seek innovative manufacturing approaches to produce PPE for healthcare workers, including 3D printing, to respond to increased demand and overall interruptions to the global supply of these products. These organizations may include those that do not traditionally manufacture PPE, such as research and academic institutions, and other industry sectors.

While Health Canada supports efforts to increase the availability of PPEs for frontline healthworkers, organizations should be aware that the manufacture of medical devices sold in Canada have technical considerations to ensure that they are safe, effective and of high quality and must meet certain regulatory standards.

Objective

This communication is intended to provide information to those intending to 3D print PPE in response to the COVID-19 crisis, in order to ensure that safe, effective, and high quality PPE are produced for Canadian healthcare workers.

The following sections provide information on:

- standards recommended by Health Canada for the production of face shields and face masks,
- the available test laboratories for product testing, and
- the relevant regulatory authorization pathways.

Standards recommended by Health Canada

Conformance with standards is voluntary for manufacturers of medical devices. A manufacturer may choose to demonstrate conformance with a listed standard or may elect to address the safety and effectiveness in another manner.

<u>Face shields</u>
A face shield is a device that has a transparent window or visor supported in front of the face to shield the eyes and face. Health Canada advises organizations who are manufacturing face shields to consult some or all of the following standards throughout the design and testing stages:

- ANSI/ISEA Z.87.1 (2015) - American National Standard For Occupational And Educational Personal Eye And Face Protection Devices

- CSA Z94.3 (2020) - Eye and face protectors
- CSA Z94.3.1 (2016) - Guideline For Selection, Use, And Care Of Eye And Face Protectors

Face masks

There are certain technical challenges associated with 3D printing certain PPE, such as face masks, to ensure safety and effectiveness. 3D-printed face masks may provide a physical barrier, but are unlikely to provide the same fluid barrier and air filtration protection as licensed surgical masks or N95 respirators. Health Canada advises organizations that are manufacturing face masks that the following standards should be consulted:

- ISO 22609 (2004) - Clothing for protection against infectious agents Medical face masks Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
- ASTM F2100 (2019) - Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F2101 (2019) - Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- ASTM F1862/F1862M (2017) - Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity
- ASTM F2299 (2003 R2017) - Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particles Using Latex Spheres

Also, in response to the COVID-19 outbreak, the CSA Group has made a selection of relevant standards for the COVID-19 outbreak available for no-fee view access. Visit the following link for further information: https://www.csagroup.org/news/covid-19-response-standards-handbooks/.

Several relevant standards for masks, gowns, gloves, and respirators, including the ASTM F2100 (2019) and ASTM F2101 (2019) listed above, are also available at the following link:

- https://www.astm.org/COVID-19/

Testing laboratories

Product testing is required to demonstrate that 3D printed final products comply with applicable standards . The following laboratories and certification bodies are accredited by the Standards Council of Canada to test against PPE standards:

Private laboratories

- https://www.scc.ca/en/accreditation/laboratories/intertek-testing-services-na-inc-intertek-cortland-laboratory

- https://www.scc.ca/en/accreditation/laboratoires/groupe-ctt-inc-ctt-group-inc
- https://www.scc.ca/en/accreditation/laboratories/cambridge-materials-testing-limited

Product certification bodies

- https://www.scc.ca/en/accreditation/product-process-and-service-certification/safety-equipment-institute
- https://www.scc.ca/en/accreditation/product-process-and-service-certification/underwriters-laboratories-canada
- https://www.scc.ca/en/accreditation/product-process-and-service-certification/canadian-general-standards-board
- https://www.scc.ca/en/accreditation/product-process-and-service-certification/intertek-testing-services-na-inc
- https://www.scc.ca/en/accreditation/product-process-and-service-certification/ul-llc
- https://www.scc.ca/en/accreditation/product-process-and-service-certification/canadian-standards-association-operating-csa-group

Regulatory authorization

Most PPE, including face shields, are Class I medical devices if they are represented for use for medical purposes.

There are currently two regulatory pathways that allow for the distribution and sale of 3D printed Class I devices. Note that a sale generally requires the transfer of ownership of a device from one party to another and does not necessitate any transfer of money. The two pathways are:

1) The manufacturer must hold an authorization under the Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19; or
2) the manufacturer must hold a valid Medical Device Establishment Licence (MDEL)

Interim Order Process

Canada is facilitating the importation and sale of medical devices used to diagnose, treat, mitigate or prevent COVID-19. On March 18, 2020, the Minister of Health approved an Interim Order which is a mechanism available to rapidly address large-scale public health emergencies.

Manufacturers may submit an application under the provisions of the Interim Order to be granted authorization to import or sell COVID-19 medical devices. This application does not require submission of fees. Health Canada will review all COVID-19-related submissions and applications as quickly as possible while maintaining standards for patient safety. To submit an application for

authorization under the interim order, please contact the Medical Devices Directorate at hc.devicelicensing-homologationinstruments.sc@canada.ca.

For information about the licensing or authorization of medical devices in Canada, please contact the Medical Devices Directorate at hc.meddevices-instrumentsmed.sc@canada.ca.

Medical Device Establishment Licence (MDEL) Process

Anyone who wishes to manufacture, import or sell a 3D printed Class I medical device in Canada requires an MDEL unless they are:

- a retailer;
- a health care facility (as defined in the Medical Devices Regulations);
- a Class I manufacturer that imports or distributes solely through an MDEL holder; or
- an interim order (IO) authorization holder.

MDEL requirements ensure that manufacturers, importers and distributors have distribution records and procedures in place to handle complaints, submit mandatory problem reports and to conduct a recall - all of which remain essential during a pandemic.

Health Canada is fast-tracking the MDEL application process for companies that want to manufacture, import or distribute Class I products. The goal is to complete the process within 24 hours from the time a completed application is received.

Companies that need an MDEL application fast-tracked should:

- contact hc.mdel.application.leim.sc@canada.ca to obtain the MDEL Application Form (FRM-0292) or access a copy of the MDEL Application Form (FRM-0292) available on Health Canada website
- complete the form
- indicate in the subject line of the email: URGENT COVID-19 MDEL application for "-name of company"
- email the completed MDEL application form to hc.mdel.application.leim.sc@canada.ca

Minimum specifications in urgent manufacturing scenarios

Health Canada recognizes that if access to face shields becomes limited, improvised production may occur. Whenever possible, manufacturers of face shields should comply with the standards outlined above. However, in the event that **urgent** production of face shields is required in Canada, Interim Order or MDEL requirements would continue to apply and Health Canada would expect

that the following minimum specifications would be incorporated into the design and verification to ensure safe and effective face shields:

- Device must provide adequate coverage (CSA Z94.3 Sections 10.2.1/10.2.2/10.3/10.4).
- Device should made of optically clear, distortion free, lightweight materials (refer to CSA Standard Z94.3.1-16 and [1])
- Device should be free of visible defects or flaws that would impede vision (ANSI Z87.1 Section 9.4)
- The device should allow adequate space between the wearer's face and the inner surface of the visor to allow for the use of ancillary equipment (medical/surgical mask, respirator, eyewear, etc.) [1].
- Device should fit snugly to afford a good seal to the forehead area and to prevent slippage of the device [1].
- Device should withstand impact from sharp or fast projectiles (ANSI Z87.1 Section 9.2 and 9.3, CSA Z94.3 Section 10.1)
- If available, device should display anti-fog behavior on inside and outside of shield. (CSA Standard Z94.3.1-16)
- User contacting materials should provide adequate material biocompatibility (skin sensitivity and cytotoxic testing) (ISO 10993-5, 10)

Approval of Class II medical devices in Canada

This document is specific to Class I PPE, however, Health Canada acknowledges that 3D printing may evolve to manufacturing Class II medical devices, which can include medical exam gloves, breathing circuit components, and Venturi oxygen masks.

Email hc.meddevices-instrumentsmed.sc@canada.ca to enquire about device classification and the required regulatory steps if you are manufacturing medical devices that may be Class II or above.

This publication may be updated as the situation evolves.

References

[1] R. J. Roberge, "Face shields for infection control: A review," Journal of Occupational and Environmental Hygiene, pp. 235-242, 2016.

Related links

- About medical devices
- Notice: Importation or sale of ventilators - use of US FDA guidance and Canadian requirements for authorization under the Interim Order
- Optimizing the use of masks and respirators during the COVID-19 outbreak

- FDA FAQs on 3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic