HEALTH CANADA (HC) MANAGEMENT RESPONSE AND ACTION PLAN (MRAP)

In response to the recommendations of the Report on Securing Personal Protective Equipment and Medical Devices of the Auditor General of Canada to the Parliament of Canada

Report Ref. No.	OAG Recommendation	Departmental Response	Description of Final Expected Outcome/Result	Expected Final Completion Date	Key Interim Milestones (Description/Dates)	Responsible Organization/ Point of Contact (Name, Position, Tel #)	*Indicator of Achievement* (For Committee Use Only)
10.82	Health Canada should determine whether respirators are appropriately classified given that Class I medical devices are not subject to a Health Canada review for safety and effectiveness.	Agreed. While Health Canada currently regulates medical devices in accordance with a risk-based classification system, consideration could be given to providing greater pre-market oversight over some lower risk devices. Health Canada acknowledges the challenges associated with ensuring that the safety, effectiveness and quality requirements for respirators are met in situations such as the COVID-19 pandemic. Under the existing *Medical Devices Regulations*, a pre-market evaluation is not an option for Class I medical devices. However, under the Interim Order (IO) pathway, Health Canada was afforded regulatory flexibilities allowing for pre-market review of respirators. Post-market surveillance activities, including inspections, and scientific evaluations under the IO increased Health Canada's awareness of low quality respirators that have the potential to enter the Canadian market. Health Canada will specifically review the classification of lower risk devices, including respirators, in the context of the development of Agile Regulations	Health Canada has requirements in place to ensure appropriate oversight of respirators prior to authorizing their sale in Canada.	**Options Analysis -** Within one year from the end of the COVID-19 Pandemic. (date TBD) *Only as required:* **Updates to Medical Device Regulations** - Published in CGI (Fall 2023)	**<u>Pre-market Evaluation of Respirators</u>** The Department will continue to conduct pre-market evaluations of all respirator applications that are submitted under *Interim Order No. 2 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* while it is in force. **<u>Options Analysis</u>** *Deliverable* An Options Analysis will be conducted to consider how the existing classification framework could be adjusted to ensure the right level of pre-market regulatory oversight is applied to respirators, based on their risk. Considerations including: • International alignment; • Quality management system requirements; and • Impact on compliance and enforcement activities will also be analyzed in order to determine the best way to achieve the desired outcome. *Timeline* • An analysis plan will be developed in the first six months from the end of the COVID-19 pandemic. • Estimated completion within one year from the end of the COVID-19 pandemic	David Boudreau, Director General, MDD, HPFB (613-957-7285)	

Report Ref. No.	OAG Recommendation	Departmental Response	Description of Final Expected Outcome/Result	Expected Final Completion Date	Key Interim Milestones (Description/Dates)	Responsible Organization/ Point of Contact (Name, Position, Tel #)	*Indicator of Achievement* (For Committee Use Only)
		for Medical Devices. While in its infancy, this initiative is underway and will provide an opportunity to determine whether respirators are appropriately classified. Health Canada is committed to exploring options to evaluate the appropriate level of pre-market oversight of these devices. An analysis will be conducted within the year following the end of the pandemic.			*The following deliverables will be completed only as required, pending the conclusion of the Options Analysis:* **Notice of Intent** If this Options Analysis concludes that the classification framework should be adjusted, a Notice of Intent will be published to communicate to stakeholders how Health Canada intends to adjust the level of pre-market oversight applied to respirators. *Timeline* • Estimated completion within three months following completion of the Options Analysis ***Updates to Regulations*** In the context of the Agile Regulations initiative, we will consider the conclusions of the Options Analysis. Depending on the conclusions, the *Medical Devices Regulations* will be updated to include provisions to apply an appropriate level of regulatory oversight to respirators. As part of this process, stakeholders will be consulted. *Timeline* • Estimated completion within 14 months following the Notice of Intent to stakeholders		