Code Life Ventilator Challenge

Phase 1 - Preliminary requirements:

In general terms, the medical device regulatory requirements that apply to a medical ventilator in the design submission phase can be described as satisfying the following criteria:

- Electrical safety
- Clinical efficacy
- Electro-magnetic compatibility (interference and susceptibility)
- Biocompatibility
- Risk mitigation (part of an overarching risk management strategy)
- Sterilization

Specifically, for medical ventilators, the following ISO standards apply:

1) **ISO 80601-2-12:2020** Standard for Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
2) **ISO 80601-2-80:2018** Medical electrical equipment – Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
3) **ISO 5367:2014** Anaesthetic and respiratory equipment – breathing sets and connectors

Phase 2 – Requirements for finalists:

In addition to those listed above, finalists will have to adhere more formally to the following medical device standards:

1. **ISO 14971:2019** Medical Devices - Application of Risk Management
2. **IEC 60601-1:2012** Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
3. **IEC 60601-1-2:2014** Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
4. **IEC 60601-1-11:2015** Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment • Any other applicable collateral/particular standards in the IEC 60601-1: 2012 family
5. **IEC 62304:2015** Medical Device Software – Software Life Cycle Processes
6. **ISO 11137-3:2017** Sterilization of health care products
7. **ISO 11607-1:2019** Packaging for terminally sterilized medical devices
8. **ISO 10993-05:2018** Biological Evaluation of Medical Devices

Phase 3 – Manufacturing and roll out:

Regulatory agencies worldwide have implemented temporary measures for development of solutions during the COVID-19 crisis. Temporary authorizations are being granted for devices that meet a minimum standard. These should include Good Manufacturing Practice (GMP) in lieu of a formal medical Quality Management System (QMS) as well as some level of compliance to the aforementioned standards, the degree of which is as of yet to be determined.

For example, Health Canada has opened an Interim Order for authorization though the Special Access Program (https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals.html#dia) and the FDA has a fast track program in place, as well as a guidance document specially on this topic (https://www.fda.gov/media/136318/download).