NGen Next Generation Manufacturing Canada

BECOMING AN APPROVED SUPPLIER OF MEDICAL DEVICES

Medical devices ISO 13485:2016 vs ISO 9001:2015 QUALITY MANAGEMENT SYSTEM COMPARISON

NGen Canada

NGen connects Canada's strengths in manufacturing and technology with its skilled workforce to build a world-class advanced manufacturing ecosystem.

NGen's Mission: Build world-leading advanced manufacturing capabilities in Canada

AGENDA

BECOMING AN APPROVED SUPPLIER OF MEDICAL DEVICES:

MEDICAL DEVICES ISO 13485:2016 VS ISO 9001:2015

- Health Canada & the Regulation of Medical Devices
  - Megan Clumpus Senior Regulatory Affairs Officer, Bureau of Device Licensing Services, Health Canada
- Comparison of ISO 13485 and ISO 9001 Standards
  - Barbara Moser MBA P. Eng.
- Questions

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Health Canada & the Regulation of Medical Devices

Megan Clumpus
Senior Regulatory Affairs Officer
Bureau of Device Licensing Services
Medical Devices Directorate | Health Canada

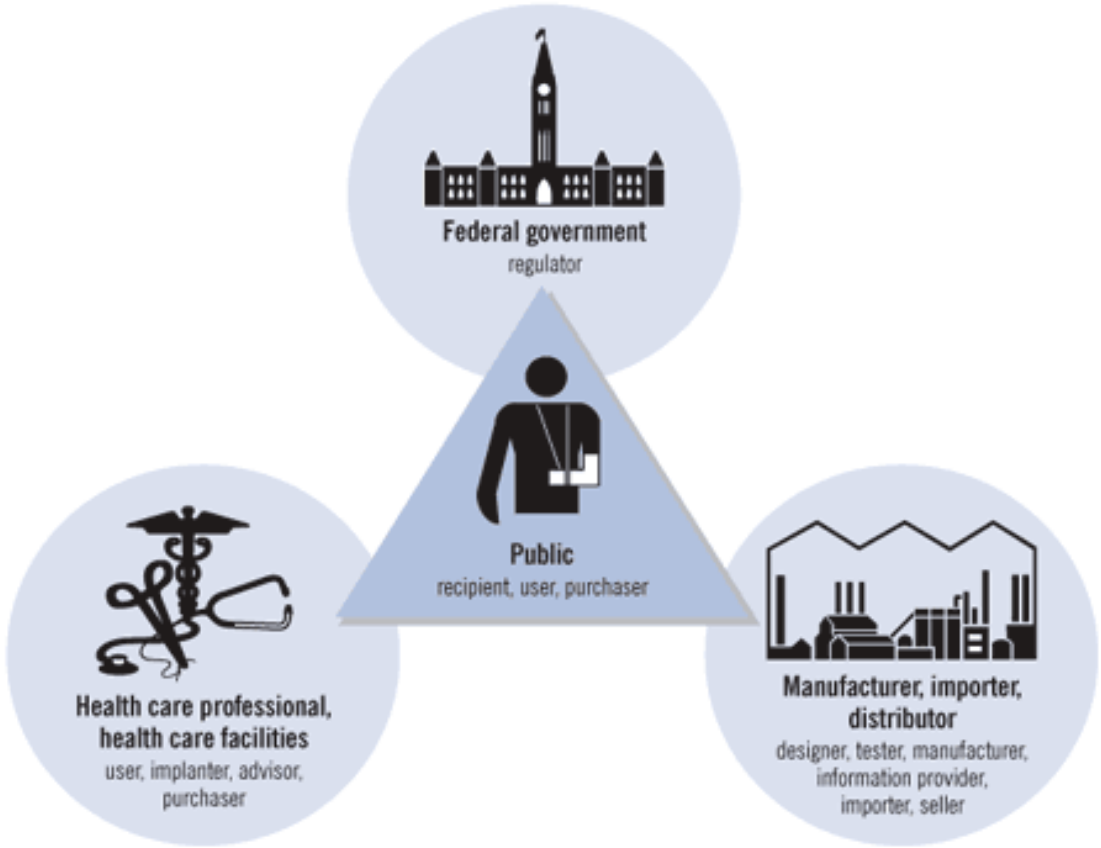


Canada

Outline

1. Stakeholders
2. Regulatory Framework
3. Licensing

Medical Device Stakeholders



Medical Devices Directorate

Senior Advisor
Catherine Dion

Director General's Office
David Boudreau

Science Advisor
Mary-Jane Bell

Bureau of Evaluation
Rosslynn Miller-Lee

- **Cardiovascular Devices**
  Kevin Day
- **Digital Health Devices**
  Marc Lamoureux
- **General and Restorative Devices**
  Constance Campbell
- **In Vitro Diagnostic Devices**
  Maria Carballo
- **Musculoskeletal Devices**
  Dr. Weimin Zhao

Bureau of ITA SAP and Post-market
Dr. Emily Hollink

- **Investigational Testing / Special Access**
  Bisi Lawuyi
- **Special Access**
  Peggy Seely
- **Post-market**
  Patrick Fandja

Bureau of Licensing Services
Colin Foster

- **Regulatory Affairs**
  Dr. Thomas Hazle
- **Regulatory Screening**
  Jade Battou
- **Device Licensing**
  Maurice Chalifour

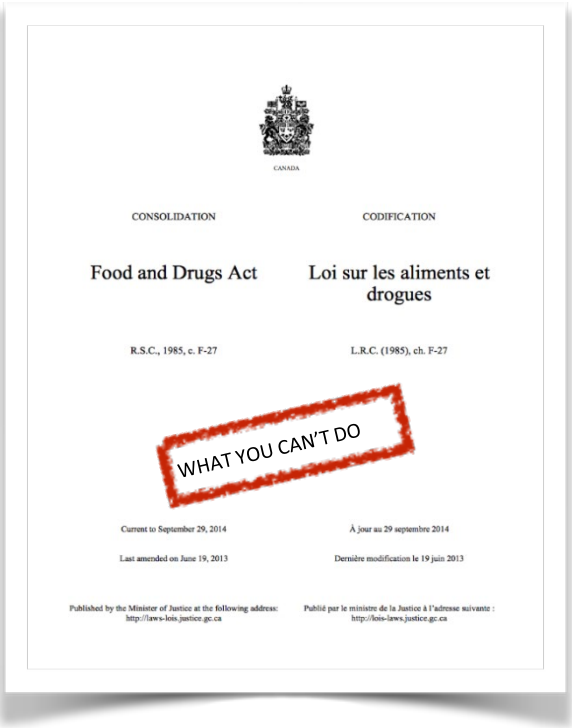
Bureau of Policy and International Programs
Saira David

- **International Programs**
  Nancy Shadeed
- **Policy**
  Vacant

Bureau of Planning & Operations
Sarah Chandler

- **Quality Systems**
  Frédéric Hamelin
- **Stakeholder Engagement**
  Brian Thornton

Health Canada's Regulatory Tools


CANADA

CONSOLIDATION | CODIFICATION

Food and Drugs Act | Loi sur les aliments et drogues

R.S.C., 1985, c. F-27 | L.R.C. (1985), ch. F-27

WHAT YOU CAN'T DO

Current to September 29, 2014 | À jour au 29 septembre 2014

Last amended on June 19, 2013 | Dernière modification le 19 juin 2013

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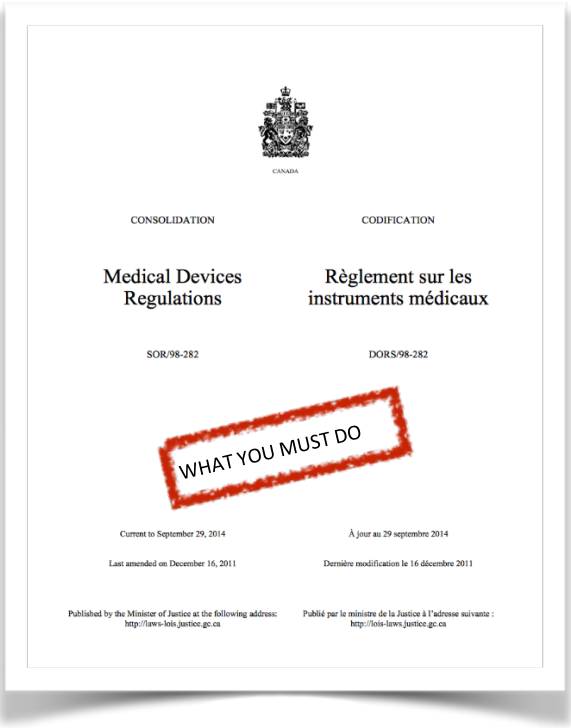
Legislation

Food & Drugs Act


CANADA

CONSOLIDATION | CODIFICATION

Medical Devices Regulations | Règlement sur les instruments médicaux

SOR/98-282 | DORS/98-282

WHAT YOU MUST DO

Current to September 29, 2014 | À jour au 29 septembre 2014

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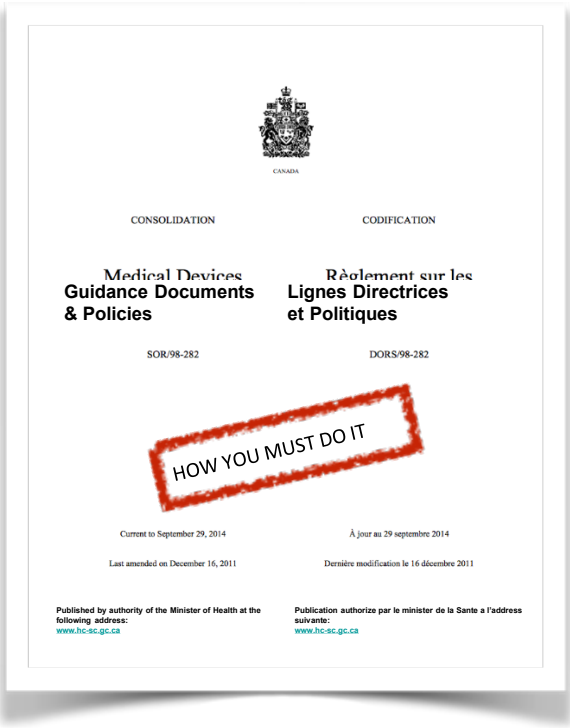
Regulations

Medical Devices Regulations


CANADA

CONSOLIDATION | CODIFICATION

Medical Devices **Guidance Documents & Policies** | Règlement sur les **Lignes Directrices et Politiques**

SOR/98-282 | DORS/98-282

HOW YOU MUST DO IT

Current to September 29, 2014 | À jour au 29 septembre 2014

Last amended on December 16, 2011 | Dernière modification le 16 décembre 2011

Published by authority of the Minister of Health at the following address: www.hc-sc.gc.ca | Publication authorize par le minister de la Sante a l'address suivante: www.hc-sc.gc.ca

Policy

Various, Updated Regularly

Food and Drugs Act

- All devices offered for sale in Canada must comply with the *Food and Drugs Act*:
  - **Section 3:** Cannot advertise to the general public or represent by label a treatment for a Schedule A disease or disorder
  - **Section 19:** Cannot sell or advertise a device that may cause harm
  - **Section 20:** Cannot sell or advertise a device in a misleading or deceptive way
  - **Section 21:** Devices must meet prescribed standards (where available)

What is a Device?

Section 2 of the ***Food & Drugs Act***:

"device" means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

(*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(*b*) restoring, correcting or modifying a body function or the body structure of human beings or animals,

(*c*) the diagnosis of pregnancy in human beings or animals, or

(*d*) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,

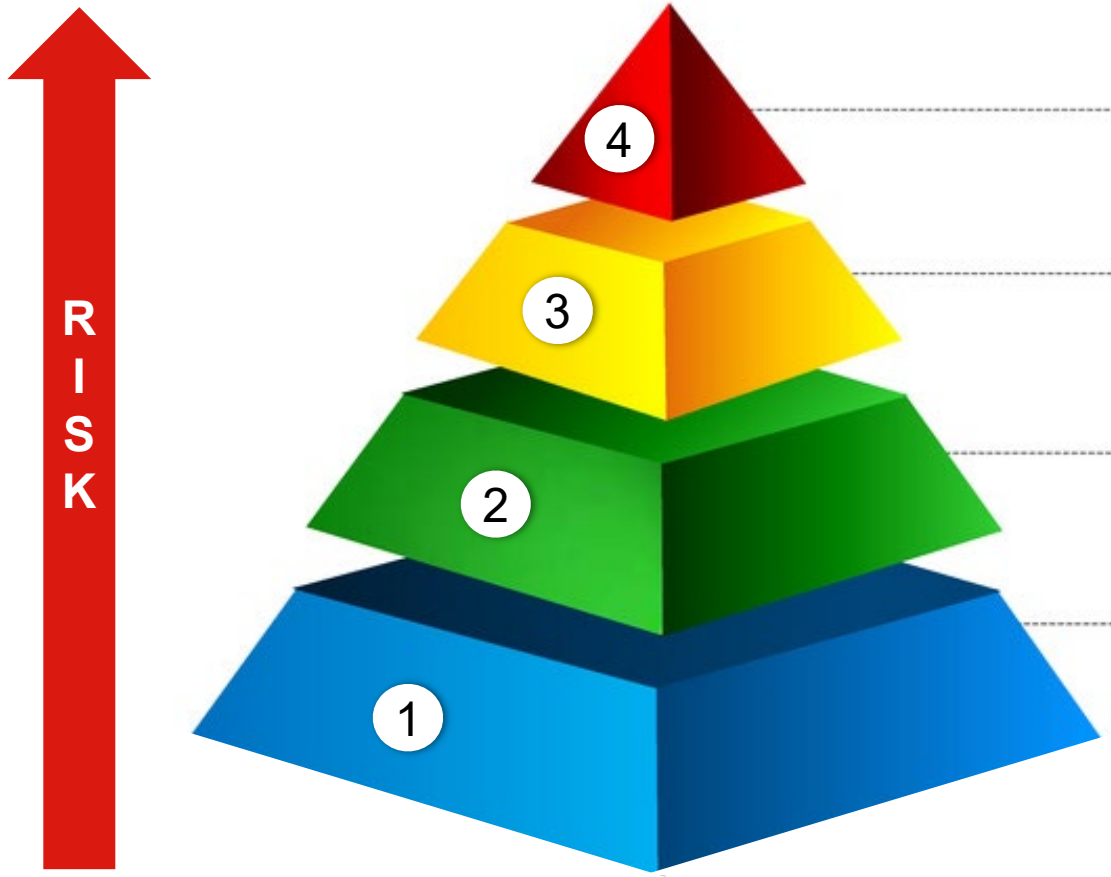
and includes a contraceptive device but does not include a drug;

The *Medical Devices Regulations* specify <u>medical</u> devices as for human use only.

Medical Devices Regulations

- **Part 1** – General
- **Part 2** – Special Access
- **Part 3** - Investigational Testing
- **Schedules**
  - 1 – Classification Rules
  - 2 – Implants
  - 3 – Export Certificates

Classification of Medical Devices



	Class I
Medical Device Licence (manufacturer)	exempt
Safety & Effectiveness (manufacturer)	keep objective evidence
Labelling (all parties engaged in importation or sales activities)	compliant label
Quality Management System Certificate (manufacturer)	exempt
Distribution Records (manufacturer, importer & distributor)	maintain record
Complaint Handling (manufacturer, importer & distributor)	maintain record
Mandatory Problem Reporting (manufacturer & importer)	submit preliminary & final report
Recall (manufacturer & importer)	submit recall notice
Establishment Licence (manufacturer (class I only), importer & distributor)	must hold active licence

	Class I	Class II
Medical Device Licence (manufacturer)	exempt	must hold active licence
Safety & Effectiveness (manufacturer)	keep objective evidence	keep objective evidence & provide attestation
Labelling (all parties engaged in importation or sales activities)	compliant label	compliant label (submit for review)
Quality Management System Certificate (manufacturer)	exempt	MDSAP certified (for manufacturing activities)
Distribution Records (manufacturer, importer & distributor)	maintain record	maintain record
Complaint Handling (manufacturer, importer & distributor)	maintain record	maintain record
Mandatory Problem Reporting (manufacturer & importer)	submit preliminary & final report	submit preliminary & final report
Recall (manufacturer & importer)	submit recall notice	submit recall notice
Establishment Licence (manufacturer (class I only), importer & distributor)	must hold active licence	must hold active licence

	Class I	Class II	Class III and IV
Medical Device Licence (manufacturer)	exempt	must hold active licence	must hold active licence
Safety & Effectiveness (manufacturer)	keep objective evidence	keep objective evidence & provide attestation	**submit** objective evidence for review
Labelling (all parties engaged in importation or sales activities)	compliant label	compliant label (submit for review)	compliant label (submit for review)
Quality Management System Certificate (manufacturer)	exempt	MDSAP certified (for manufacturing activities)	MDSAP certified (for **design** and manufacturing activities)
Distribution Records (manufacturer, importer & distributor)	maintain record	maintain record	maintain record
Complaint Handling (manufacturer, importer & distributor)	maintain record	maintain record	maintain record
Mandatory Problem Reporting (manufacturer & importer)	submit preliminary & final report	submit preliminary & final report	submit preliminary & final report
Recall (manufacturer & importer)	submit recall notice	submit recall notice	submit recall notice
Establishment Licence (manufacturer (Class I only), importer & distributor)	must hold active licence	must hold active licence	must hold active licence

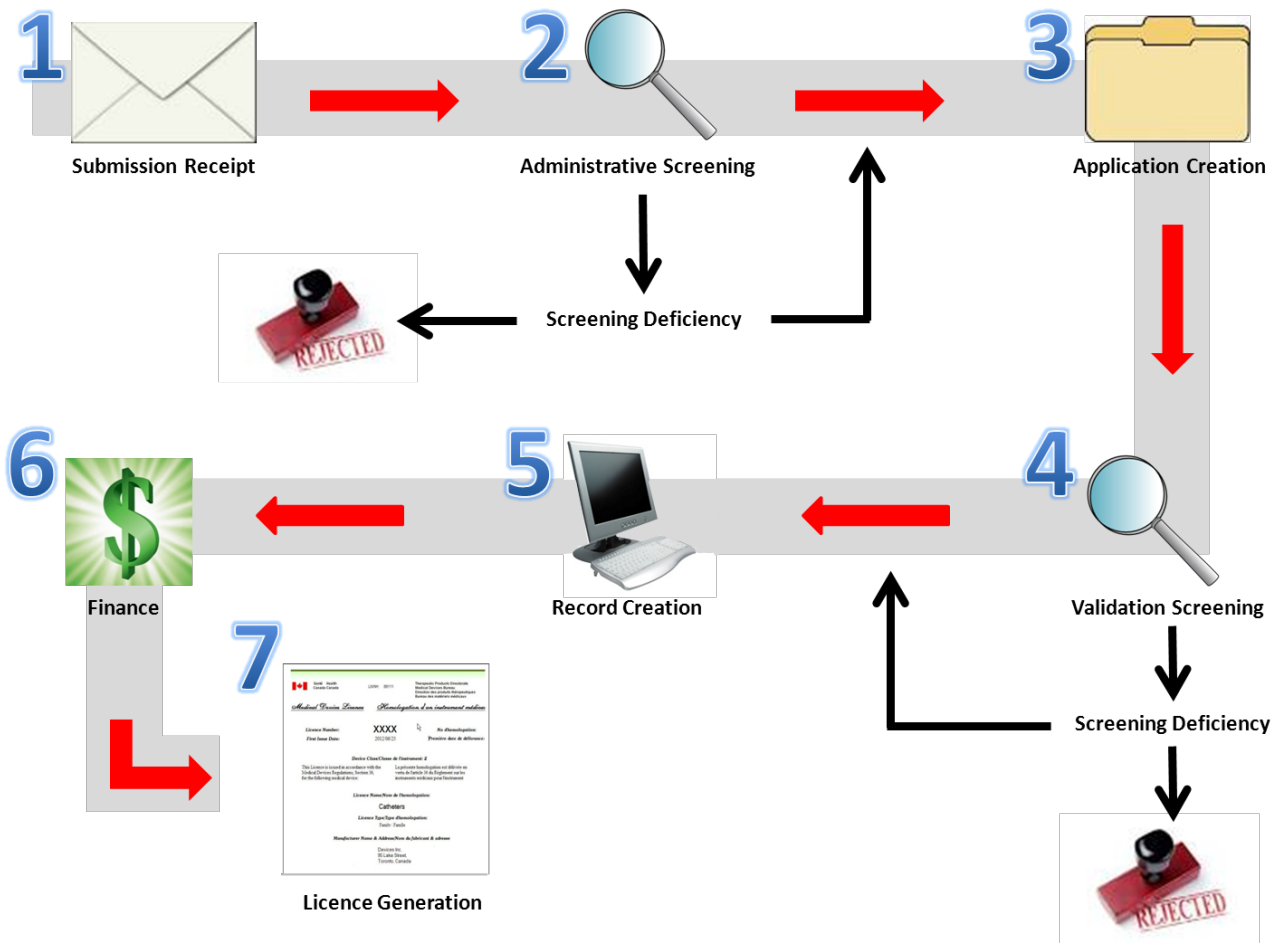
Application Process – Class I

- Please note that the Medical Devices Directorate (MDD) is not responsible for processing Medical Device Establishment Licence (MDEL) applications

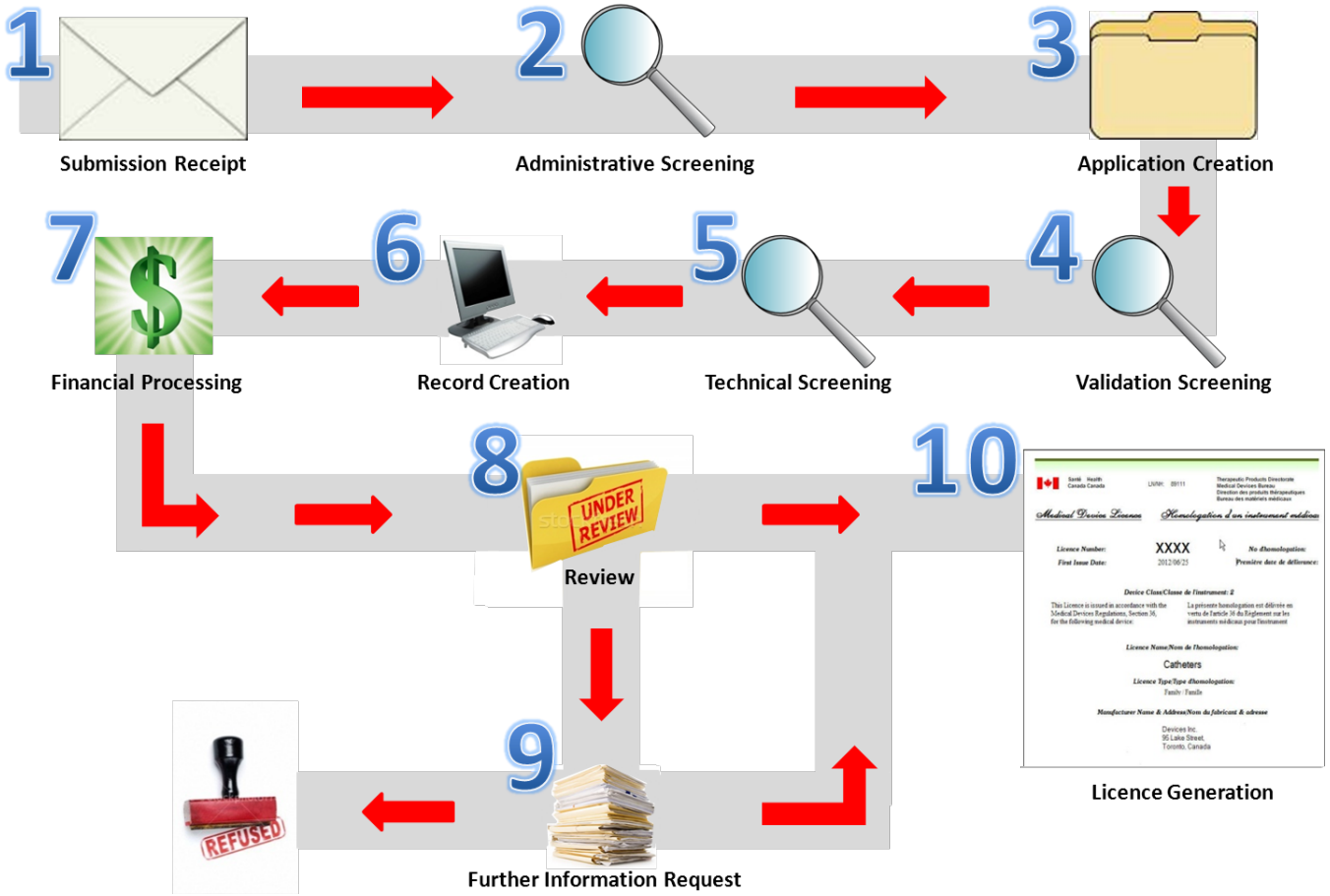
- It is recommended that you contact hc.mdel.questions.leim.sc@canada.ca for any questions regarding MDELs specifically or the MDEL application process

- More information on the MDEL process may be found here.

Application Process – Class II



Application Process – Class III & IV



Thank you for your time

If you have any questions in the future, please contact our office directly at:

hc.meddevices-instrumentsmed.sc@canada.ca

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Medical devices ISO 13485:2016 vs ISO 9001:2015 QUALITY MANAGEMENT SYSTEM COMPARISON

Presented by Barbara K. Moser, MBA, P.Eng.

AGENDA

BECOMING AN APPROVED SUPPLIER OF MEDICAL DEVICES:

MEDICAL DEVICES ISO 13485:2016 VS ISO 9001:2015

1. INTRODUCTION
    - PRESENTER & TOPIC
        - WHITEPAPER SCOPE AND OBJECTIVE OF THE SEMINAR
    - THE BROADER CONTEXT
    - EVOLUTION OF ISO 9001
    - IMPLEMENTATION OPTIONS
2. TECHNICAL CONSIDERATIONS
    - THEMES
    - HIGHLIGHTS OF ISO 13485:2016 SECTIONS
3. CONCLUDING REMARKS

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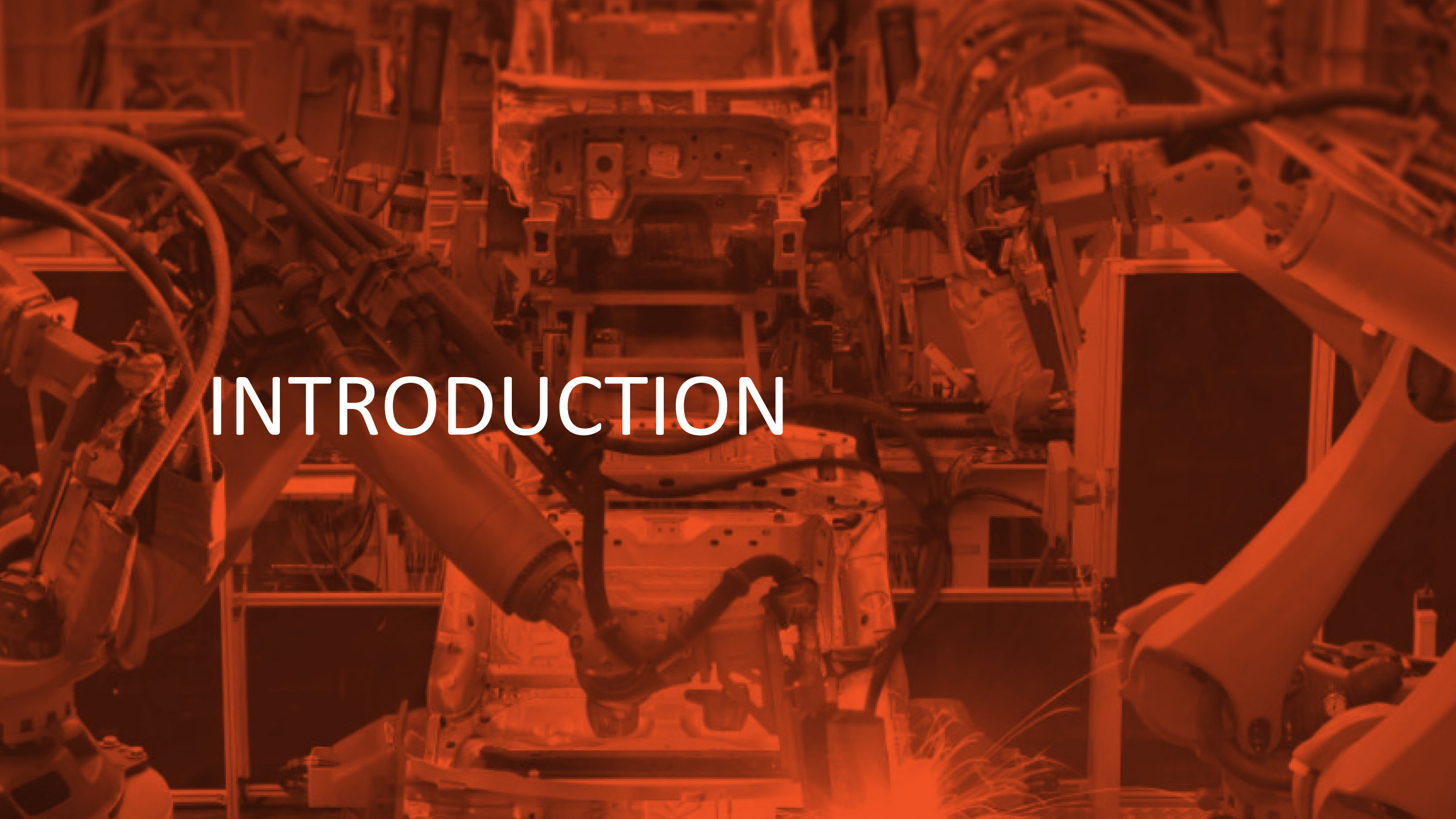

INTRODUCTION

Topic Outline

- Reference material for today's presentation
  - Whitepaper has been prepared to cover a detailed clause-by-clause comparison of ISO 13485:2016 vs ISO 9001:2015 Quality Management System (QMS) requirements
  - Whitepaper includes a correlation matrix, with corresponding clause numbers and comments comparing contents of the two (Appendix A)
  - Whitepaper lists additional considerations for entering the medical devices manufacturing field (Appendix B)
  - Whitepaper is available for download on NGen.ca website

Scope and Objective of the Seminar

- Underlying assumption: the organization is currently a manufacturer of a tangible good and holds an approved ISO 9001:2015 QMS certification

- Webinar and whitepaper aim to be useful tools in the organization's quest to fulfill ISO 13485:2016 Quality Management System requirements

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The Broader Context (aka Macro Considerations)

- Understand and Define the Context of the Organization
  - The organization needs to revisit its context and the scope by determining the external and internal issues that are relevant to its (new) purpose and strategic direction. They will be changing along with the product offering.
- List All Interested Parties: especially Customer Base
  - The organization must acknowledge the expectations of interested parties and add customer-specific obligations to scope.

The Broader Context (aka Macro Considerations)

- Define Supply Base
  - In addition to reviewing purchasing process requirements, the organization must determine if the existing supply base is suitable for the new product offering.
- Risk Assessment
  - In ISO 13485:2016 “risk” pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements. The term “risk” is used in ISO 9001:2015 to describe risk-based thinking, which applies to the organization as a whole in an effort to address risks and opportunities to increase the effectiveness of the QMS, improve results and prevent negative effects.

Evolution of ISO 9001

- Origin of ISO 9001 (late 1980's)
    - Purpose was to harmonize the various quality standards in existence for manufacturing organizations
    - Feedback was that it was too narrow in its focus (i.e. manufacturing)
- Patterned on "4 Tier Documentation Model"
    - Tier 1: Policy
    - Tier 2: Procedures
    - Tier 3: Work Instructions
    - Tier 4: Records and Forms

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Evolution of ISO 9001

- ISO 9001 was adopted by various industries (e.g. manufacturing, service, distribution) within the industry sectors
- Some industry sectors elected to use the ISO 9001 standard as its base and apply specific supplemental requirements
- Latest revision is ISO 9001:2015
- Medical devices chose to use previous version ISO 9001:2008 as a base for ISO 13485:2016

Implementation Options

- Fundamental Question
  - Does the organization want to have two stand-alone QMS' for the sectors or one , integrated QMS for the entire organization?
- Two Stand-alone QMS
  - Pro's: may be easier to create and easier to audit
  - Con's: may lead to nonconformances if have two standards for one workforce
- Hybrid QMS
  - Challenges: different ISO 9001 revision as base; different product/process requirements

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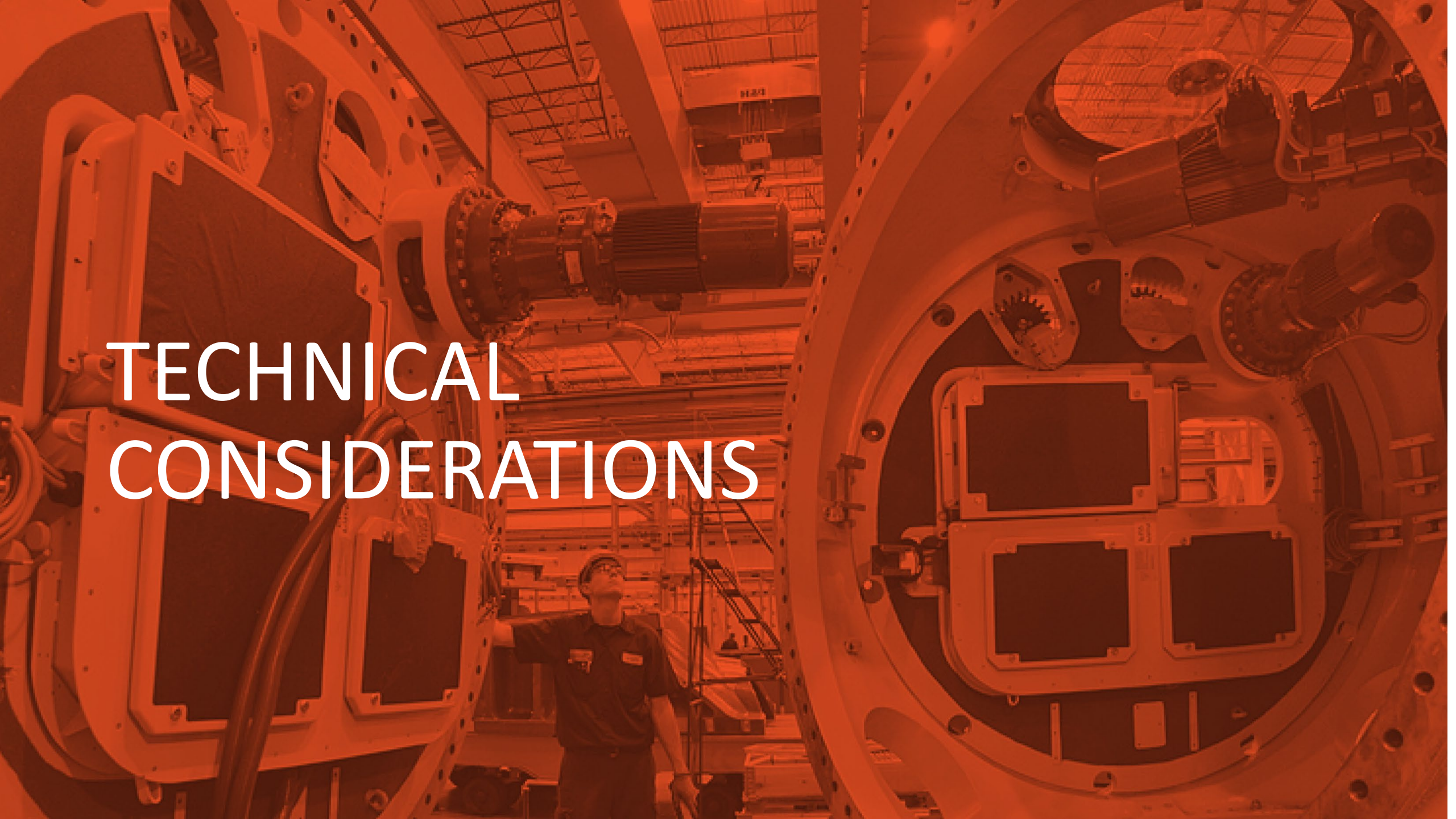

TECHNICAL CONSIDERATIONS

Technical Considerations: Themes

- Numbering System and Title Nomenclature
  - ISO 13485 uses the numbering systems and title nomenclature from ISO 9001:2008; ISO 9001:2015 conventions are different
- Documentation Requirements
  - Because documentation requirements were more prescriptive in ISO 9001:2008 there are more mandatory requirements for documented procedures in ISO 13485
- Environmental Controls
  - ISO 13485 has very stringent cleanliness requirements which may or may not be compatible with environmental controls in ISO 9001:2015
- Specific Medical Devices Manufacturing Requirements
  - Manufacturing requirements (e.g. product files), end user requirements/liabilities

Technical Considerations: Section Highlights

1 Scope

- The organization must identify and establish the boundaries and context of the organization with respect to incorporating medical devices into its product offerings
- Some aspects of ISO 9001:2015 4.1 Understanding the Organization and Its Context affect the scope.

Technical Considerations: Section Highlights

4 Quality Management System

- ISO 13485 4.1 Quality Management System covers the roles undertaken by the organization, discusses QMS processes, their interactions and risk assessments that are required. The section also outlines the requirements for resources, planning, operation, controls, monitoring and measurement together with records for QMS processes. The section discusses change control for QMS processes, the need for control, validation and risk assessment for software used in QMS processes.

- ISO 13485 4.2 Documentation Requirements covers quality manual; medical device file; control of documents and control of records.

- Careful review of section is required to determine the extent to which the ISO 13485 requirements are covered in the ISO 9001:2015 QMS

Technical Considerations: Section Highlights

5 Management Responsibility

- ISO 13485 5 Management Responsibility covers management commitment, customer focus, Quality Policy, planning (including Quality Objectives),internal communication, management representative and management reviews. In essence, top management must demonstrate leadership and commitment with respect to the QMS by taking ownership and accountability for the effectiveness of the QMS. Furthermore, top management has to ensure that the Quality Objectives align with the organization's strategic direction.

Technical Considerations: Section Highlights

6 Resource Management

- Section covers infrastructure, human resources and work environment. The organization is task with providing the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS. ISO 13485 6.5 Work Environment and Contamination Control makes special mention of cleanliness requirements required during the production process, as well as during packaging and handling of the product.

Technical Considerations: Section Highlights

7 Product Realization

- The requirements of section 7 cover all aspect of providing a product from contract/order review, planning of necessary resources, design and development, obtaining goods and services from external sources, manufacturing processes, product verification, handling, storage, shipping and after-market support (including end user training) as required.

- ISO 13485 7.5 Production and Service Provision includes additional requirements for cleanliness and handling provisions which apply specifically to the medical devices being produced.

Technical Considerations: Section Highlights

8 Measurement, Analysis and Improvement

- The section covers all aspects of measurement, including customer satisfaction and feedback, reporting to regulatory authorities, internal audits, monitoring and measurements of products and processes, control of nonconforming products and improvement including both preventive and corrective actions.

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CONCLUDING REMARKS

Concluding Remarks

There are many benefits which result from implementing a well-structured Quality Management System. First and foremost is that it fosters product integrity. But in addition, an effective Quality Management System is a solid foundation for a world-class Business Management System.

Every requirement and every recommendation in the ISO QMS standards has been carefully considered and debated for countless hours by highly skilled technical committees. Incorporating and actioning the requirements is so much more than just an exercise in “ticking off the boxes”. It is a blueprint for success.

Barbara K. Moser, MBA P. Eng.
BK Moser Consultants
barbara.k.moser@bkmoser.com


Questions?

NGen Next Generation Manufacturing Canada

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