INSTITUTE OF QUALITY MALAYSIA
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IQM President's Viewpoint:
Business Prospects of Quality Practitioners (Malaysia)

(2021/2023)

The Quality Management System (QMS) has been developing in a very dynamic manner for the past 20 years. It (QMS) has been applied by Quality Practitioners in various business sectors and numerous industries. Following are the summaries of the Quality element existing in these diversified industries under various standards and technical requirements. Due to recent pandemic (Covid-19) the whole manner of quality business in Malaysia is entering into a challenging phase.

(A) Healthcare industry, including medical device, medical laboratory & pharmaceutical products and hospital engineering facilities

The healthcare industry is one of the industries that places significant attention on the issue of "Quality" in relation to healthcare services and healthcare products especially in mitigating and preventing further pandemic Covid-19 outbreak. The areas of "Quality" application shall include healthcare facilities such as hospitals, medical laboratories, and medical gas piping system. The healthcare products shall include medical devices, PPE, medical masks, pharmaceutical products, Quality Environment and Indoor Air Quality are essential elements. There are numerous opportunities for IQM members to participate in this healthcare industry.

The relevant standards, technical and regulatory requirements are:-

1) ISO 13485 "Medical Device – Quality Management Systems – Requirements for Regulatory Purposes". This shall include Medical Face Mask and Ventilator.
2) ISO 15189 "Medical Laboratories – Particular Requirements for Quality and Competence". Include Diagnostic Tests for Covid-19 (RT-PTC).
3) ISO 14971 "Medical Devices – Risk Management Application".
4) Joint Commission (USA) International Standards for Hospitals.
5) Food & Drug Administration (FDA) (USA) Regulatory Requirements.
6) European (EC) Regulatory Requirements – Medical Device Directives.
7) MS 2058:2009 "Code of Practice for Good Engineering Maintenance Management of Active Medical Devices".
8) Pharmaceutical Good Manufacturing Practices (GMP) and Drug Regulatory Requirements. Other important Requirements include Sterilization & Sanitization.
9) ISO 17024 "Conformity Assessment – General Requirements for Bodies Operating Certification for Persons".
10) MS 2299:2010 "Medical Gloves for Single Use: Part 1 to Part 3".
11) Other International requirements, such as WHO, USA FDA, British MHRA.
12) Malaysia "Medical Devices Act 2011" & Regulations (2012).

All the above standards, legislation, technical requirements are basically consist of "Quality elements in various healthcare products and services.

(B) Energy Industry, Green Building and IT Security

The recent global Climate Change has resulted in worldwide Governments of various countries to pass laws and make legislations, so that they can control and govern the Energy Consumption with minimum impact on Climate Change or rather "Quality Climate" Sustainability. The Energy Sector shall include Oil & Gas Industry and Power Generation Industry.

The "Quality" governance aspects shall include "Carbon Emission", "Green Technology", "Energy Efficient Management", "Renewable Energy", "Alternative Energy",…etc.

The latest development in Malaysia, the focus is on "Green Township", "Green Rating System", "Green Building Index", "Energy Saving",…etc. All those activities open up new business opportunities and employment opportunities for individual IQM members and IQM Company members.

IT security is also very important in the rapid development of Information Technology Sector and the Digital World. Especially in servicing society to mitigate pandemic Covid-19 spreading.

The relevant laws, regulations, technical standards and best practices are:-

1) Energy Commission Act 2001 Malaysia (Act 610).
2) Efficient Management of Electrical Energy Regulations 2008.
3) MS 1525:2014 "Code of Practice on Energy Efficient and use of Renewable Energy for Non-Residential Buildings.
4) ASNI/ASHRAE Standard 90.1-2019 "Energy Standard for Buildings except Low-Rise Residential Buildings".
5) Chartered Institute of Building Services Engineers (CIBSE)(London) "Energy Efficiency in Buildings" (Latest Edition).
6) CIBSE TM22 "Energy/Assessment and Reporting Methodology – Office Assessment Method" (Latest Edition)
7) Green Building Index (GBI) Assessment Criteria (PAM and ACEM Malaysia).
8) ISO 50001: Energy Quality Management Systems Requirements.
9) ISO/TS 29001: QMS Sector Specific to Petroleum & Natural Gas industries.
10) ISO 3834: Quality Requirements for fusion welding of metallic materials.
11) ASME BPVC and API 1104. The relevant quality management activities.
12) ISO 27001: Information Security Management System.
13) ISO 22301: Business Continuity Management System.
14) ISO/TS 22163: Railway Application: Quality Management System.

Recent pandemic Covid-19 outbreak has had detrimental effects on the Transport Industry Globally.

(C) Environmental Quality, Sustainable Palm Oil, Mining Industry and consequential requirements (eg. Water & Air Quality)

The recent virus (Covid-19) pandemic outbreak illustrates the importance of Occupational Safety and Health, Indoor Air Quality and Hygiene in the healthcare industry worldwide.

However, the recent Climate Change has imposed global challenges to the World. In Malaysia, since 2003, the attention of Environmental Quality has widen the scope to include "Air Quality", "Water Quality", "Sustainable Palm Oil", "Green Palm", "Green

Purchase", "Green Mining", "Biofuel", "Biodiversity Loss", "Life Cycle Assessment" and "Green Market/Product".

In the case of Sustainable Palm Oil, it is anticipated that IQM Members, as a Quality Practitioners, are able to participate in the quality Inspection and Auditing aspects. Especially in the RSPO and MSPO Inspection and Auditing activities.

The relevant laws, legislations, codes and standards and best practices are:-

1) Environmental Quality (Clean Air) Regulations 1978.
2) Industry Code of Practice on Indoor Air Quality (2010) (DOSH) (MOHR).
3) Environmental Quality (Schedule Wastes) Regulations 1989/2005.
4) Environmental Quality (Effluent) Regulations 2009.
5) Water Services Industry Act 2006 (Act 655).
6) Suruhanjaya Perkhidmatan Air Negara (SPAN) Act 2006.
7) MS 2320:2010: Drinking Water – Quality Requirements.
8) ISO 14001: Environmental Management Systems (EMS) Requirements.
9) ISO 45001: Occupational Health and Safety Management Systems (OH&S).
10) MS 2530:2013: Malaysia Sustainable Palm Oil (MSPO).
11) Green Mining Initiative and international best practices.
12) ISO 45005: OH&S: General Guidelines for Safe Working during Covid-19 pandemic.

(D) Facility Management, Food Industry and Occupational Health & Safety Requirements

In the year of 2018, three prominent Standards are revised and issued by ISO, namely:-

ISO 41001: Facility Management Systems - Requirements with Guidance for use (April 2018)

ISO 22000: Food Safety Management Systems - Requirements for any organization in the food chains (June 2018)

ISO 45001: Occupational Health and Safety Management Systems – Requirements with Guidance for use (March 2018) (Include ISO 45005 in 2020)

The above new ISO Standards (FMS, FSMS and OH&SMS) provide opportunities and challenges to IQM Members in their business development, especially in providing better quality services to their clients and expand their business to gain more clients, both locally and globally.

IQM wishes all Members good luck and prosperous business in future years.

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