



INSTITUTE OF QUALITY MALAYSIA
Registration No. 2423 (Selangor)

IQM 30th AGM

(Sept 2010)

President Message,

Roles of IQM for the next Decade 2010 ~ 2020

For the next decade IQM has the responsibility to move forwards together with its members to face the new global challenges, and provide a platform for the members to advance their professional career and business opportunity to a more diversified quality fields. Beside the traditional quality management system (QMS ie ISO 9001:2008), food quality HACCP, and quality control activities, there are other areas of quality activities in the following fields:-

- (1) Healthcare industry, including medical device, medical laboratory & pharmaceutical products.
- (2) Energy industry, including efficient energy management and renewable energy.
- (3) Environmental quality and consequential requirements.

It is necessary to note that Energy, Palm Oil and Healthcare are 3 of the 12 National Key Economics Areas (NKEA) identified in the recent Malaysian Government's Economic Transformation Programme (ETP).

All IQM members shall not miss the chance to share this economic pie!

(1) Healthcare industry, including medical device, medical laboratory & pharmaceutical products

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. 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, and pharmaceutical products. There are numerous opportunities for IQM members to participate in this healthcare industry.

The relevant standards, technical and regulatory requirements are:-

- 1) ISO 13485:2007 "Medical Device – Quality Management Systems – Requirements for Regulatory Purposes".
- 2) ISO 15189:2004 "Medical Laboratories – Particular Requirements for Quality and Competence".
- 3) ISO 14971:2001 "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) ISO 17021:2006 “Conforming Assessment – Requirements for Bodies providing Audit and Certification of Management Systems”.
- 8) MS 2058:2009 “Code of Practice for Good Engineering Maintenance Management of Active Medical Devices”.
- 9) Pharmaceutical Good Manufacturing Practices and Drug Regulatory Requirements.
- 10) ISO 17024:2003 “Conformity Assessment – General Requirements for Bodies Operating Certification for Persons”.
- 11) ISO 7396:2007 “Medical Gas Pipeline Systems”.
- 12) MS 2299:2010 “Medical Gloves for Single Use: Part 1 to Part 3”

(2) **Energy industry, including efficient energy management and renewable energy**

The recent global Climate Change has resulted in worldwide Governments in various countries to pass laws and make legislation, so that they can control and govern the Energy Consumption with minimum impact on Climate Change.

The 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.

The relevant laws, regulations, technical standards/practices are:-

- 1) Energy Commission Act 2001 Malaysia (Act 610).
- 2) Efficient Management of Electrical Energy Regulations 2008.
- 3) MS 1525:2007 “Code of Practice on Energy Efficient and use of Renewable Energy for Non-Residential Buildings.
- 4) ANSI/ASHRAE Standard 189.1-2009 “Standard for the Design of High-Performance Green Building” (except Low-Rise Residential Buildings).
- 5) ASNI/ASHRAE Standard 90.1-2004 “Energy Standard for Buildings except Low-Rise Residential Buildings”.
- 6) Chartered Institute of Building Services Engineers (CIBSE)(London) “Energy Efficiency in Buildings” 2004.
- 7) CIBSE TM22:2004 “Energy/Assessment and Reporting Methodology – Office Assessment Method”.
- 8) Green Building Index (GBI) Assessment Criteria:2009 (PAM and ACEM Malaysia).

(3) **Environmental Quality and consequential requirements**

Traditionally, the Environmental Quality business opportunities for quality practitioners are always limited to Environmental Quality Audit and related consulting activities, especially in the Environmental Impact Assessment Study, since 1994 until 2003.

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”, “Biofuel”, “Biodiversity Loss”, “Carbon Credit Trading”, “Life Cycle Assessment”, “Ecolabelling” and “Green Market/Product”.

This has provided a wide scope of opportunities for IQM members to participate in various “Green” related activities.

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

- 1) Environmental Quality Act 1974 (Act 127).
- 2) Environmental Quality (Clean Air) Regulations 1978.
- 3) Code of Practice on Indoor Air Quality (2005), Department of Occupational Safety and Health, Ministry of Human Resource, Malaysia.
- 4) Environmental Quality (Schedule Wastes) Regulations 1989/2005.
- 5) Environmental Quality (Sewage) Regulations 2009.
- 6) Environmental Quality (Effluent) Regulations 2009.
- 7) Water Services Industry Act 2006 (Act 655).
- 8) Suruhanjaya Perkhidmatan Air Negara (SPAN) Act 2006.
- 9) ISO 14040: Life Cycle Assessment.
- 10) ISO 14020: Labelling & Marketing.
- 11) ISO 14062: Design for Environment.
- 12) ISO 14001: Environmental Management Systems (EMS) Requirements.
- 13) MS 2320:2010: Drinking Water – Quality Requirements.

Conclusion

It is the aim of IQM to put in place a Business Plan for the next few years to focus on the above opportunities for the IQM Individual and Company members, together to achieve high-income status.

Individual Involvement as Professionals

- 1) Auditors, Specialists, Quality System Assessors,...etc.
- 2) Managers, Coordinators, Document Controllers,...etc.
- 3) Consultants, Advisors, Purchasers,...etc.

Company Involvement

The Company involvement may include:-

- 1) Manufacturing of healthcare products or pharmaceutical products.
- 2) Operation of healthcare facilities, such as hospitals or medical laboratories.
- 3) Certification and Assessment Bodies that provide Third Party Independent Certification and Assessment Services.
- 4) Consultancy and Advisory Services.
- 5) Manufacturing of Energy related equipment and Construction of Energy related engineering facilities.
- 6) Manufacturing of Water & Sewage related equipment and Construction of Water & Sewage related engineering facilities.

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