ISO 9001:2015 Quality Management System Standard (QMS)

- Brief Introduction to ISO organization

- Benefits of ISO standards

- Some definitions

- PDCA (Plan-Do-Check-Act) Cycle

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ISO – International Organization for standardization

ISO – in Brief

- ISO is an independent, non-governmental international organization with a membership of 161 national standards bodies.
- Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

ISO – Standards

- ISO has published 22062 International Standards and related documents, covering almost every industry, from technology, to food safety, to agriculture and healthcare.
- Most popular ISO Management System Standards are:
    - QMS: Quality [9001]
    - EHS: Environment, Health & Safety [14001]
    - ISMS: Information Security [27001]

Benefits

- ISO International Standards ensure that products and services are safe, reliable and of good quality.
- For business, they are strategic tools that reduce costs by minimizing waste and errors and increasing productivity.
- They help companies to access new markets, level the playing field for developing countries and facilitate free and fair global trade.

Some Common Definitions

- Quality
- Management
- Standard
- System
- Management System
- Risk & Risk Management

Quality

- The adjective quality applies to objects and refers to the degree to which a set of inherent characteristics fulfills a set of requirements.
- The quality of an object can be determined by comparing a set of inherent characteristics against a set of requirements. If those characteristics meet all requirements, high or excellent quality is achieved but if those characteristics do not meet all requirements, a low or poor level of quality is achieved.

Management

- The term management refers to all the activities that are used to coordinate, direct, and control organizations.
- These activities include
    - developing policies,
    - setting objectives, and
    - establishing processes to achieve these objectives.

Standard

- a level of quality or attainment.
    - synonyms: quality, level, grade, degree, worth, caliber, merit, excellence
- something used as a measure, norm, or model in comparative evaluations.
- used or accepted as normal or average.

System & Management System

- A system is defined as a set of interrelated or interacting elements.
- A management system is one type of system. It is a set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are needed to ensure that policies are followed, and objectives are achieved.

Risk

- Risk is "effect of uncertainty on an expected result"
- An effect is a positive or negative deviation from what is expected.
- Whenever we try to achieve something, there's always the chance that things will not go according to plan. Sometimes we get positive results and sometimes we get negative results and occasionally we get both.
- We need to reduce uncertainty as much as possible.
- Uncertainty (or lack of certainty) is a state or condition that involves a deficiency of information and leads to inadequate or incomplete knowledge or understanding.

Risk in context of Risk Management

- In the context of risk management, "uncertainty exists whenever the knowledge or understanding of an event, consequence, or likelihood is inadequate or incomplete."
- "the term risk is more commonly used when there is only the possibility of negative consequences".

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