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(17-12-2014, Vienna, Austria)

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Problems faced in implementation of ISO 9001:2008 and GS-R-3 in Nuclear Organizations and Identification of Improvement Areas.
1. INTRODUCTION TO QMS
2. IMPLEMENTATION OF QMS
3. IMPROVEMENT OF QMS
4. BENEFITS OF QMS IMPLEMENTATION
5. LESSONS LEARNED
6. SUMMARY
1. INTRODUCTION TO QMS (Cont...)

- THE MANAGEMENT SYSTEM:
  - The Management System is a set of interrelated or interacting elements that establishes policies and objectives and which enables those objectives to be achieved in a safe, efficient and effective manner. (IAEA, GS-R-3, 2006)

- QUALITY MANAGEMENT SYSTEM:
  - The Management System to direct and control an organization with regard to Quality (ISO 9000:2005)

1. INTRODUCTION TO QMS (Cont…)

COMPARISON OF ISO 9001:2008 & IAEA GS-R-3
1. INTRODUCTION TO QMS (Cont...)

QMS REQUIREMENTS:


- **QMS Documentation** includes:
  Quality Policy, Quality Manual, Quality System Procedures (QSP), System Operating Procedures (SOPs), Quality Records.

- **QMS Requirements**
QMS IMPLEMENTATION

1. INTRODUCTION TO QMS (Cont...)

- QMS IMPLEMENTATION:
  - Development of Documentation Infrastructure (2012)
  - Implementation started in 2013
  - Certification of QMS in 2014
QMS IMPLEMENTATION

2. QMS IMPLEMENTATION

- SCHEDULE OF QMS IMPLEMENTATION:
  - Documentation Infrastructure Development (2012)
  - Effective Implementation started in Jan 2013
  - Progress Monitoring meetings were carried out on monthly basis
  - Internal Quality Audits conducted in 2013 & 2014
  - Management Reviews were conducted in 2013 & 2014
  - After Implementation Certification body was hired.
  - Certification Audit was conducted in 2014, and recommended for ISO 9001:2008 Certification

2. QMS IMPLEMENTATION (Cont...)

- PROBLEMS IN QMS IMPLEMENTATION:
  - Problems for Difference in Requirements (ISO 9001:2008 & IAEA GS-R-3)
  - Problems for Awareness of QMS Requirements
  - Problems with the Documentation
  - Problems of Non-implementation of Data Analysis

2. QMS IMPLEMENTATION (Cont...)

- **PROBLEMS IN QMS IMPLEMENTATION:**
  - Problems for Difference in Requirements (ISO 9001:2008 & IAEA GS-R-3)
    - ISO 9001:2008 permits exclusions to the requirements of its clause 7.
    - No exclusion is permitted from GS-R-3 Requirements only Grading can be made to the requirements.
    - QMS includes: EXCLUSIONS to “Design and Development Clause (7.3), Validation of processes (7.5.2) and Control of Monitoring & Measuring Equipment (7.6)”. 
2. QMS IMPLEMENTATION (Cont...)

- The requirements of GS-R-3 for Grading of the activities, Safety Culture and Self Assessment are not mentioned in ISO 9001:2008

- Solutions taken include:
  - The requirements of GS-R-3 not addressed in ISO 9001:2008 were included as additional requirements in QMS.
  - If any new work assignment is added the requirements of process control (7.5.1) are applied.
  - These include availability of procedures and work instructions, monitoring and measurement requirements etc.
  - The records of new work assignment and inspections are maintained.

2. QMS IMPLEMENTATION (Cont…)

- PROBLEMS IN QMS IMPLEMENTATION:
  - Problems for Awareness of QMS Requirements
    - The resistance to change specially in the early beginning in some areas because of lack of awareness of QMS.
    - Sensitivity to issue the nonconformities and application of corrective actions
  - Solutions adopted:
    - QMS Awareness Sessions were conducted to communicate the importance of implementing QMS.
    - Guidance was provided to aware the persons that non-conformities are chances of improvement
Problems with the Documentation:

- The nature of the organization work from the beginning where hundreds of documents accumulated.
- The challenge was to adjust these documents and include them in the Quality Management System.

Solutions adopted include:

- During the documentation identification stage, the necessary documentation was identified and only relevant documents were included in Quality Management System (QMS).
2. QMS IMPLEMENTATION (Cont...)

- Problems of Non-implementation of Data Analysis
  - The factual approach to the management requires data collection and its analysis regarding system, process and product / services.
  - This importance was not realized in some areas thus lacking to address the QMS requirements for improvement based on data analysis.

- Solutions adopted include:
  - The indicators/parameters for the service were identified. The process was monitored by the Quality Steering Committee.
  - This resulted in improvement by decisions of management to use efficient resources based on data analysis.
3. IMPROVEMENT OF QMS

- IMPROVEMENT THROUGH INTERNAL AUDITS
  - Identification of Improvement Areas
  - Corrective & Preventive Actions

- CONTINUAL IMPROVEMENT
  - Methods for Improvement
QMS IMPLEMENTATION

3. IMPROVEMENT OF QMS (Cont...)

☐ IMPROVEMENT THROUGH AUDITS

- **Internal Audits** are conducted as per defined frequency of once per year for each Division

- Auditors were IRCA, UK Certified Lead Auditors for ISO 9001:2008 QMS.

- **External Audits** are conducted once a year by Certification body.
3. IMPROVEMENT OF QMS (Cont...)

- **Identification of Improvement Areas**
  - **Internal Audits** have been conducted in 2013 & 2014. It includes the Divisions (consisting of 04 technical and 02 support divisions).

- The results of these Internal audits are summarized below:
  - **2013** - Total Non-conformances issued = 43
  - **2014** – Total Non-conformances issued = 28
QMS IMPLEMENTATION

3. IMPROVEMENT AREAS –DQA (Cont...)

- External Audit (Certification Audit) was conducted by Certification body in 2014.
  - Total Non-conformances issued=04 Nos.
Based on the Internal Audit Results the following Areas for Improvement in QMS were Identified:

(For year 2013)

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<tbody>
<tr>
<td>Control of Documents</td>
<td>4.2.3</td>
<td>5.12</td>
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<tr>
<td>Process Control</td>
<td>7.5.1</td>
<td>5.3, 5.9</td>
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<tr>
<td>Analysis of Data</td>
<td>8.4</td>
<td>6.1*</td>
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<td>Quality Objectives</td>
<td>5.4.1</td>
<td>3.8*</td>
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<td>Training</td>
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<tr>
<td>Control of Records</td>
<td>4.2.4</td>
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<td>Quality Policy</td>
<td>5.3</td>
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<td>Customer Satisfaction</td>
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<td>Responsibilities</td>
<td>5.5.1</td>
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Based on the Internal Audit Results the following Areas for Improvement in QMS were Identified:

(For year 2014)

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* Not specifically covered

3. IMPROVEMENT OF QMS (Cont...)

- Corrective & Preventive Actions
  - The **Areas of Improvement** were identified through the conduct of Internal Audits every year.
  - The Corrective Actions were identified by addressing the root causes and implemented within one month duration.
  - Any finding if required more than one month for implementation of corrective action was discussed with top management.
  - Afterwards, Corrective Action suggested was implemented.
  - Follow-up was made for verification of effectiveness of actions taken and findings were closed.
CONTINUAL IMPROVEMENT

- Methods for Improvement
  - The Internal Audit Results were reviewed (as input to the Management Reviews) and the Areas for further Improvement in QMS were identified (using Pareto Chart) for factual decisions.
  - The status of implementation of Corrective & Preventive Actions for identified findings was monitored (for their implementation).
  - The Quality Objectives were developed every year and monitored for implementation.
CONTINUOUS IMPROVEMENT

- Methods for Improvement
  - The Analysis of Data was conducted for processes/services of every Division.
  - The Customer Feedback was collected for service processes and it was analyzed.
  - The Management Reviews were conducted every year after completion of internal audits to review the effectiveness of QMS by top management.
4. BENEFITS OF QMS IMPLEMENTATION

- KEY BENEFITS OF QMS
- BENEFITS TO THE EMPLOYEES
- BENEFITS TO THE ORGANIZATION
4. BENEFITS OF QMS IMPLEMENTATION

KEY BENEFITS OF QMS:

- Standardization of work processes
- Performance improvement of organisation
- Problem solving and continual improvement of processes
- Efficient use of Resources
- Reduces costs
- Boosts Moral
- Increases customer satisfaction
- Increases profit
4. BENEFITS OF QMS IMPLEMENTATION

- Better Understanding of Responsibilities and Authorities.

- Efficient Management System causing Reduced Stress Levels.

- Increased Morale and Sense of Pride.

- Quick Awareness of the Job for the New Staff.

- Easily pin points the bottlenecks.
4. BENEFITS OF QMS IMPLEMENTATION

- To make products/services more acceptable internationally.
- To satisfy customer’s contractual requirements.
- To reduce the number of second party audits.
- To gain a competitive advantage by improving the quality of products and services.
- To harmonize product/service and business practices worldwide.

4. BENEFITS OF QMS IMPLEMENTATION

- BENEFITS TO THE ORGANIZATION

  - To sustain competitiveness through the continuous quality improvement cycle.
  - To improve returns of investment through correct use of operating procedures, equipment, customer complaints procedure, corrective and preventive action.
5. LESSONS LEARNED

The following requirements of IAEA GS-R-3, should be included in MS as Additional Requirements:

- Safety Culture by developing and promoting MS
- Grading the Application of Management System Requirements
- Self Assessment

(Reference: Safety Series Report No. 69, Management System Standards)
b) Management System (MS) **Awareness Sessions** should be conducted to communicate the importance of implementing MS.

c) The emphasis should be given to the **Identification and Development of Documentation Infrastructure** for effective implementation of MS.

d) The role of **Quality Action Teams** should be of prime importance for establishing, implementing and maintaining the MS.

e) The **Methods for Continual Improvement** (including audit results, analysis of data, corrective and preventive actions, and management reviews) should be implemented for an effective MS.

6- SUMMARY

- INTRODUCTION
- IMPLEMENTATION OF QMS
- IMPROVEMENT AREAS
- BENEFITS OF QMS
- LESSONS LEARNED
- SUMMARY
THANKS