DEPARTMENT OF NUCLEAR TECHNOLOGY
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CIDA COURSE ON QUALITY MANAGEMENT

"ESTABLISHING QUALITY MANAGEMENT (QM)"

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1. Objective Of Presentation :

This presentation will discuss the key elements of QM program and methods of its implementation.
Specifically, the following will be discussed :

- contents and structure of the QA program
- format and content of typical procedures
- implementation of the QM program

2. Introduction .

2.1 It is generally recognized that quality of performance is achieved in an effective, timely and productive manner when it is built into day-to-day operations. Therefore it is desirable to have **line organization** with a strong sense of **responsibility for the quality of performance.**

2.2. Quality requirements must be integrated into daily work. For this integration to be successful, personnel performing the work have to be provided with the information , skills, tools , support and encouragement to properly carry out the assigned tasks. It is incumbent on management to define requirements, train, motivate and empower personnel, and to assess performance.

2.3 A quality assurance program is often interpreted as only a regulatory requirement and additional paperwork, with no real impact on the overall performance.

2.3 Such an interpretation is incorrect. Quality assurance program should be seen instead as the necessary component of **quality management** which, when properly applied, will make a significant difference in the way work is done at the plant.

2.4 Quality assurance program, through its content, defines the key requirements and policies which, when rigorously applied, will enable management to focus its attention and direct its efforts towards achieving excelience. The main thrust of QA program is meeting quality objectives through prevention of errors and defects.

2.5 Quality Assurance focuses on performance and encompasses all managerial, performance and assessment activities. It is a vital part of management strategy to enhance quality, safety and economics of an operation through efficient utilization and coordination of resources.

2.6 All the key resources must be coordinated : people, documentation and equipment, and all must be working in the same direction - towards improving quality of performance.

3. Organizational Structure .

3.1 In order to establish clear accountability for performance of functions and for results, the organizational structure shall be clearly defined. Lines of authority and communication shall be indicated and ease of communication shall be maximized.

3.2 Definition of organization and of the responsibilities of all departments shall be a part of the plant's Quality Assurance manual.

3.3 Each department should prepare a summary of its duties, responsibilities and outputs. All coordinating responsibilities shall be highlighted.
The following shall be included :

- statement of responsibilities and key performance areas
- definition of quality requirements and the means of achieving it
- definition of performance measures and the method of monitoring them

4. Policies and procedures.

4.1 Quality assurance programme consists of a series of documents which are arranged in three categories :

- **programme description,** being the statements of quality policy and plant and corporate objectives
- **programmatic procedures,** being the administrative documents describing the key management functions necessary for the functioning of the quality system, for example verification or corrective action procedure
- **detailed working procedures** which define how work shall be done, for example maintenance or operating procedures

4.2 Preparation of procedures is a difficult process, requiring careful balance between the mandatory and the desirable requirements. Generally speaking, procedures should specify mandatory requirements only and offer an outline of what the desirable requirements might be.

4.3 It is important that people who have to implement the procedures be given opportunity to input into their preparation. This is one of the ways which ensure that procedures are "user friendly".

4.4 The fact that a procedure has been written and duly approved and issued will not necessarily result in its universal and correct application. Detailed **training in procedures** and continued emphasis on their application are necessary. This training should be formalized and repeated at appropriate intervals. Training sessions are a good opportunity to identify ways in which procedures can be improved, based on the input of users.

4.5 A **procedure compliance policy**[1] shall be in place. It shall be supported by broad training such that individuals understand significance of their duties and the consequences of mistakes arising from misconceptions or lack of diligence.

4.6 **Upkeep of procedures is very important.** Work of good quality can rarely be consistently performed if procedures are known to be incorrect. Staff will attempt to compensate for them and take short-cuts, resulting in inevitable mistakes.

5.Interfaces [2].

5.1 Many activities at a plant require cooperation of a number of organizations inside and outside the plant .Interaction between them takes place at the so-called "interfaces" which must be controlled and optimized.

5.2 Interfacing organizations must recognize that the safe, reliable and economical operation of the plant is the ultimate objective of the organization. Outside organizations- such as those providing support functions- also recognize that their activities must be complementary to the performance objectives of the plant.

5.3 Formal interfaces **within the plant** include :

- need to include operations staff in preparation and review of operating and maintenance procedures
- having the responsible shift crews verify procedures and plans
- shift crews having to provide formal feedback on the appropriateness and ease with which plans/procedures have been executed

5.4 There are also important formal interfaces with other **organizations outside the plant** which provide support functions , such as

- corporate support groups such as engineering
- contractors and consultants

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[1] *procedure compliance policy* : defines the requirement to comply with the letter and intent of procedures. Specifies the need for formality and attention to detail in all activities.

[2] *interface* : a common boundary between two departments at which co-operative interactions are required between two or more organizations in order to execute an activity

These organizations recognize that their activities must be complementary to the performance objectives of the plant

5.5 These interfaces should be governed by **formal "interface procedures[3] "** , which should incorporate the following elements :

- definition of responsibilities and authority of all parties involved in the interaction
- preparation of independent but compatible and complementary procedures to govern execution of activity in each department involved
- review and approval of each other's procedures

6. Grading of QA processes[4]

6.1 The extent to which QA requirements are to be applied should be consistent with the operational significance of the item, service or a process. A graded approach is desirable which can satisfy the necessary and appropriate requirements for each item and at the same time ensure the required quality.

6.2 The objective of grading is to identify the components essential for safety, economy and reliability and to concentrate on those. Other components and services will be required to satisfy less stringent quality requirements which are nevertheless adequate for their importance and function.

6.3 Quality level for activities within the plant shall be selected using defined criteria, including engineering judgment and operational experience. The highest level of quality should be used when inadequate control of activities during operations could result in undue risk to operations personnel, the plant or the product.

7. Deficiencies and corrective actions[5].

7.1 An effective program for dealing with deficiencies and corrective actions is a pre-requisite to satisfactory and long-term operation.

In the absence of an effective and structured program to identify and resolve deficiencies, they could accumaulate to the point where safe and reliable operation would be jeopardized. At that point managment would have lost control of plant configuration by not knowing what is in satisfactory working order and what is not.

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[3] *interface procedure* : a written procedure (agreement) between the interfacing organizations, defining their relative functions and responsibilities

[4] *graded quality requirements* : specific QA requirements reflecting planned and recognized differences for each identified item, service and process

[5] *corrective action* : action taken to correct the root cause of an identified deficiency

7.2 Deficiencies can develop in a number of areas , such as :

- performance
- equipment
- procedures and documentation
- personnel (training)
- software
- quality program

7.3 Identified deficiencies/problems often require detailed review and analysis to determine the **"root cause " of the deficiency**. This analysis is sometimes complicated and lengthy, but nevertheless is absolutely necessary if the deficiency is to be resolved permanently.

7.4 To determine whether the deficiency/corrective action **process meets expectations,** it is necessary establish meaningful measures of performance.
Typical performance measures might be :

- number of outstanding corrective actions
- number of corrective actions behind schedule
- percentage of completed corrective actions rejected during assessment
- number of repeated deficiencies
- percentage of deficiencies occurring in certain categories ,e.g. procedures
- timelines of completion of corrective actions

8. Verification.

8.1 The **purpose of verification** is to confirm that work has been correctly performed. The need and extent of verification is determined by critical analysis of the task and consequences of errors. More rigorous verification should be applied to activities where errors would result in unsafe conditions or to complex tasks where the likelihood of error is high (grading of quality requirements).

8.2 Verification shall be applied to items, activities , services and processes, such as, for example ;

- operating activities in the plant
- maintenance activities in the plant and in the maintenance shop
- preparation of documentation, procedures and plans
- chemical and other analysis
- engineering calculations
- computer software etc.

8.3 A document defining the verification function shall be prepared and **training shall be periodically conducted** to ensure that all staff understand the verification concept and the procedure for its application.

9. COMPETENCE OF PERSONNEL.

9.1 The matter of assuring continued competence of personnel is of primary importance to management , and the QA program must define the requirements which will ensure satisfactory performance in this key area as follows.

9.2 A long-term training and qualification plan shall be developed for the organization, with the objective to :

- develop
- maintain
- upgrade

the knowledge and skills of the staff.

9.3 All personnel shall be **qualified** for their positions and **competent** to execute their assigned tasks before work is assigned. Their competence shall be confirmed by periodic testing or evaluating their recent pertinent experience.

9.4 Achievement of competence must be demonstrated both with respect to knowledge and skills. **Skills,** once acquired, **must be kept up**, and therefore there shall be a program of refresher training. This program will define the periodic re-training requirements and frequency. Examinations to confirm continued proficiency in a skill shall be part of this re qualification program .

9.5 All personnel, including senior management should receive **training in Quality fundamentals, practices and the basic tools of quality.**
This shall include training in QA procedures, such as, for example:

- verification
- self assessment and auditing
- corrective action

This training shall be periodically augmented through refresher courses, topical seminars and case studies.

10. Document Control And Records.

10.1 **Documents** are the paper or computer instructions which convey information about how work should be executed or provide references necessary to execute work. When documents cease to be immediately useful - after the work has been completed, - they become **records** which provide historical reference, evidence and assurance about the quality of the work .

10.2 Changes to documentation and computer software shall be carefully controlled to prevent unauthorized changes, damaging , disturbing or destroying of information.

10.3 Quality of documentation shall be **periodically assessed**. Typical performance measures are:

- number of performance errors where procedural deficiencies have been identified as a significant factor
- % of procedures which have not been reviewed when they should have been
- difficulty of locating documentation within a reasonable time frame
- % of procedures found to contain significant errors
- amount of feedback from the field with respect to procedures - the more the better

11. OPERATING EXPERIENCE .

11.1 The nuclear industry operates several data banks to record and disseminate operating experience. Both good practices and adverse events are recorded.
Information on specified kinds of events are fed into these data banks operated by international operating organizations (IAEA, WANO). This information is generally available throughout the industry. This information should be used to avoid repetition of mistakes made elsewhere .

11.2 For effectiveness ,the **operating experience (OPEX) program** at a utility must satisfy the following conditions :

- pertinent information must be screened in a consistent, systematic and timely manner
- significant ("consequential ") events or conditions which apply to the utility must be made available promptly to the appropriate people at the power plants
- these events must be investigated to find root causes
- if further review at the power plants is required, the questions to be asked are :
  - do conditions exist at our plant for a similar event to occur?
  - if so, what can be done to prevent this from happening ?
- required corrective actions, if any ,must be implemented in accordance with the appropriate priority
- the information should be incorporated into training materials, so its lessons will continue to be applied.
- all of the above actions should be documented for future reference
- effectiveness of OPEX program should be periodically reviewed and assessed,

12. QA Program Implementation

12.1 Elements of the implementation process:

- implementation plan :
- management commitment :
- quality program implementation committee
- programmatic procedures

- communications

12.2 Activities to be started after initial implementation :

- declare QA program "in effect"
- self assessment
- audits and surveillance
- corrective actions
- performance measures
- review of effectiveness of QA program

12.3. Typical difficulties encountered during implementation :

- middle management not convinced of the need for QA program,
- lacking hard data to demonstrate shortcomings
- not appreciating the extent of effort required
- lack of understanding of daily implications of management commitment
- inability to correct problems permanently
- lack of understanding of the role of QA dept., line responsibility and the significance of Quality Management in the power plant

12.4 What would we do differently at Ontario Hydro?

- obtain hard evidence of less than satisfactory performance
- more education and training at all levels
- start self assessments sooner to identify weak spots and to gain commitment to improvement
- enforce the need to correct problems permanently
- focus teams on business needs and process improvement

12.5 Results achieved

- new organization, which includes all essential functions
- business relationship with outside departments
- working relationships improved
- gradual, but uneven improvement in performance, as demonstrated by the various performance measures
- increased familiarity with Quality Management concepts and acceptance for the need to improve
- efficient identification of deficiencies, but uneven performance with respect to correction of root causes
- preparation and maintenance of good documentation

<u>This Is A Long-Term Project And Results Are Slow In Coming.</u>

13. Role Of The Quality Group .

13.1 The **plant manager is the "champion "** of the quality management program. It is his program and he must carry the responsibility for its effectiveness.

13.2 The quality group should **never make the mistake of accepting ownership** and responsibility for the quality program. Notwithstanding the above, the **quality group** at the plant has a vital role to play - they **are the "keeper "**of the quality program, while the plant manager is the "champion ".

13.3 The quality group's objectives at the plant are as follows:

- independently assess the effectiveness of management processes as they apply to plant performance
- assess effectiveness of the various processes comprising the Quality Assurance program
- provide expert advice to plant management on matters pertaining to the Quality Improvement Program (QIP)
- maintain and update the QA program
- assist the manager in defining and pursuing the objectives of QIP
- conduct and coordinate audits and assessments

13.4 General comments:

- get away from paperwork and compliance with regulations- address performance problems
- coordinate QA with other quality initiatives, such as QIP
- offer practical advice on what needs to be done for effectiveness, i.e. for results.
- focus on the long term and gradually, continuously improve the various QA processes.

Words Are Not Sufficient,
Results Are The Only Thing That Counts.

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