

Canadian Regulatory Oversight of Management Review

Regional Workshop on the development and implementation of effective IMS based on GSR Part 2

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Regulatory Activities Section Division of Nuclear Installation Safety International Atomic Energy Agency (IAEA) Department of Nuclear Safety & Security

nuclearsafety.gc.ca





 Provide an overview of the Canadian Regulatory expectations and approach to verification of licensees Management Review process

• To share some good practices and improvements as observed by the Canadian Regulatory staff at the licensees.



- CNSC: Canadian Nuclear Safety Commission
- CSA: Canadian Standard Association
- IAEA: International Atomic Energy Agency
- ISO: International Standard for Organization
- SCA: Safety and Control Areas
- SpA: Specific control areas

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Introduction

- Evolution of Management Review
- Management Review process, including:
 - Importance of Management Review
 - ✓ CNSC Regulatory Framework and Requirements
 - Leaders Regulatory Expectations
 - ✓ CNSC staff expectations for management review
 - CNSC staff oversight, experience and observations
 - Conclusion and Key Messages

Introduction (1)

- A management system is based on a framework of generic elements common to many specific management systems. These generic elements are:
 - policy
 - planning
 - implementation and operation
 - performance assessment
 - management review
 - improvement



All management system standards have a requirement for the organization to conduct a review of the management system for effectiveness



What is a management system?

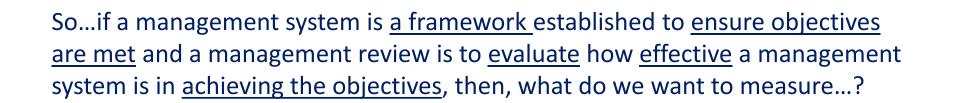
• A management system is the framework of processes, procedures and practices used to ensure that an organization can fulfill all tasks required to achieve its objectives safely and consistently

What is management review?

 A regular and systematic evaluation by senior management* of the suitability, adequacy, effectiveness and efficiency of its management system in executing the policies and achieving the goals and objectives of the organization.

* **Senior management** means the person who, or group of people which, directs, controls and assesses an organization at the highest level. This is equivalent to "Top Management" used in other standards, most notably ISO and CSA N286.





Evolution of Management Review (1)

From...ISO 9001 1987 "the Standard Companion"...

4.1.3 Management Review

Top Management Reviews and Supports Compliance with the Quality System

- Responsibility of top management to review the results of internal audits, their ensuring corrective actions and other pertinent quality-related information to ensure the continuing effectiveness of the quality system.
- Internal audits done on a rotating schedule cover each area at least once a year. The ISO 9001 Management Representative summarizes the results and reviews the results with top management. Management also reviews customer complaints and other pertinent quality-related data such as manufacturing yields, and direct measures of customer satisfaction. Management is expected to support follow-through on identified corrective actions.

Evolution of Management Review (2)

To...GSR Part 2 " Leadership and Management for Safety"...

• 6.1. The effectiveness of the management system shall be monitored and measured to confirm the ability of the organization to **achieve the results** intended and to identify **opportunities for improvement** of the management system.

 6.6. Senior management shall conduct a review of the management system at planned intervals to confirm its suitability and effectiveness, and its ability to enable the objectives of the organization to be accomplished, with account taken of new requirements and changes in the organization.

- 6.7. The management system shall include evaluation and timely use of the following:
 - lessons from experience gained and from events that have occurred, both within the organization and outside the organization, and lessons from identifying the causes of events
 - technical advances and results of research and development
 - lessons from identifying good practices

Evolution of Management Review (3)

To...CSA N286 "Management System Requirements for Nuclear Facilities"...

- Management shall **continually improve the management system**. The following shall be carried out:
 - trend analysis of causes and problems
 - periodic critical assessment of the effectiveness of the management system to achieve the planned results
 - benchmarking the **performance and experience of others**, where practicable
 - maintaining awareness of changes in its business environment
 - seeking opportunities to improve processes

Evolution of Management Review (4)

To....ISO 9001:2015 "Quality management systems-Requirements"

9.3 Management review

9.3.2 Management review inputs

The (top) management review shall be planned and carried out taking into consideration:

- a) the status of actions from previous management reviews
- b) changes in external and internal issues that are relevant to the management system
- c) information on the performance and effectiveness of the management system, including trends in
 - 1) customer satisfaction and feedback from relevant interested parties;
 - 2) the extent to which objectives have been met;
 - 3) process performance and conformity of products and services;
 - 4) nonconformities and corrective actions;
 - 5) monitoring and measurement results;
 - 6) audit results;
 - 7) the performance of external providers;
- d) the adequacy of resources
- e) the effectiveness of actions taken to address risks and opportunities
- f) opportunities for improvement

That's a lot of important information to review and internalize.

Management Review Process (1)

Outcome of management review evolution shifted From:



 Senior management determining the effectiveness of the management system based just on the internal audit results and their ensuring corrective actions and other pertinent quality-related information, where focus are mostly product oriented.

To:

- Senior management conducting periodic critical assessments of the management system at set intervals to confirm its suitability and effectiveness, and its ability to achieve set objectives, taking into consideration of new requirements and changes in the organization and to continually identify opportunities for improvement of the management system.
- A set of baseline criteria required to be reviewed are defined



Management Review Process (2)

- The management review is an activity key to the "Check" component within the Plan-Do-Check-Act model of effective management systems.
- Management review is a dynamic and ongoing process for improving operational and corporate programs and processes
- Management review is an element in most, if not all management systems standards.











Importance of Management Review

- Allows Senior Management:
 - To review and make decisions based on key information provided to

them.



To confirm with confidence the status of effectiveness of their management system and how well it is working in meeting the organization's planned results.



CNSC Regulatory Framework and Requirements

- The CNSC Regulatory Framework and requirements comprises of 14 safety and control areas (SCAs).
 - one of the 14 SCAs is the Management System
- The Management System SCA:
 - Covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture
- The Management System SCA comprises of 10 specific control areas (SpA) one of which includes:
 - Performance assessment, improvement and management review.

CNSC Regulatory Framework and Requirements

CNSC licence condition for Management System for Class I Nuclear Facilities:

- CAN CSA N286-12, Management System Requirements for Nuclear Facilities
- CSA N286-12 standard emphasizes:
 - Top management is responsible for the implementation and continuous improvement of their facility's management system.
- CSA N286-12 standard requirement is:
 - To conduct management reviews with sufficient frequency to confirm that the management system is effective in meeting the planned results and business objectives.
 - Continually improve the management system

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Leaders Regulatory Expectations (1)

Senior leaders' regulatory expectations:

- Top management is accountable for the management system
- Senior management shall demonstrate leadership for safety
- Top management shall define, plan, and control the business so there is alignment and integration.
- •A process shall be defined that
 - creates purpose, such as vision and values
 - identifies relevant requirements to be met
 - establishes objectives that achieve the requirements
 - Identifies and controls risks to the objectives
 - establishes plans, measures, and targets

measures and monitors to ensure the planned results are achieved.

Assessments, audits management review



Leaders Regulatory Expectations (2)

Top management is expected to adhere to a set of **management system principles** as the basis of their management system:

- Safety is the paramount consideration guiding decisions and actions
- The licensed activities are defined, planned and controlled
- The organization is defined and understood
- Resources are managed
- Communication is effective
- Information is managed
- Work is managed
- Problems are identified and resolved
- Changes are controlled
- Assessments are performed
- Experience is sought, shared and used
- The management system is continually improved

These principles and associated core management processes are fundamental to an effective management review

These principles are the basis of the core management processes within the management system.



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CNSC expectations for management review (1)

Expectations of management review activities from licensees include:

- Reviewing, assessing, and measuring performance against objectives and requirements and reporting the results by top management.
- Inputs to the management review assessments should be verifiable and include but not limited to:



- Review of self assessments and independent assessment results to confirm performance and adherence to the management system requirements
- Review of established key performance indicators that measures the effectiveness of activities, criteria for analysis input data and the analysis method for assessing of the program and process effectiveness

CNSC expectations for management review (2)

- Review results of the data analysis, including assessment against regulatory, legal and other requirements and performance objectives for health, quality, safety, security and the environment.
- Review of incident investigations, corrective actions, trending data, operating experience and improvement actions status and its adequacy



evaluate the need for changes to the management system, including its
scope and principles, as well as the organization's structure and resources.

CNSC expectations for management review (3)

- Expectations of management review outputs from licensees include:
 - Top management periodic assessment of the effectiveness of the management system critically to achieve the planned results
 - Results of the data analysis used to arrive at stated conclusions regarding the effectiveness of the management system including resources, changes to the organization and management system
 - Trend analysis of causes, problems and the corrective and improvement actions that are identified to address the problems
 - Opportunities for improvement



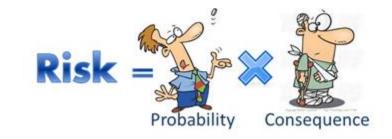
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CNSC expectations for management review (4)

- Planned actions to address any weaknesses in the management system are identified by the review
- ✓ The persons responsible for the implementation of the improvement actions have been identified and timelines have been established for completion.
- ✓ All activities important to safety have been reviewed
- Individual(s) who performed the review and date of review.

CNSC staff oversight, experience and observations (1)

- CNSC staff conduct management review compliance activities at the licensees as one of the management system oversight activities
- The frequency and extent of compliance activities take into consideration the complexity and safety significance of licensed activities



CNSC staff oversight, experience and observations (2)

• Good practices observed from licensee management reviews:

- Independent oversight of program assessment process
- Use of existing assessment results and trending data
- Assessment peer-reviewed and accepted by manager
- Functional area assessments independently verified, presented and validated by top management quarterly or at annual meetings
- Management system, human performance and safety culture metrics considered together
- Corrective actions incorporated into the business plan
- All corporate and functional programs assessed



CNSC staff oversight, experience and observations (3)

Opportunities for improvement for management reviews:

- A management review should ensure:
 - There is information from trend analysis of problems, audit and assessment findings, and corrective actions; less reliance on solely using performance indicators
 - Stated conclusions are supported by sufficient information
 - Performance indicators include considerations of process performance
 - Management reviews cover all the programs that impact safety
 - The management review addresses findings and corrective actions from the previous year's report
 - ✓ All core elements or principles are assessed



CNSC staff oversight, experience and observations (4)

Opportunities for improvement for management reviews:

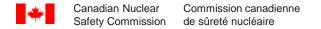
- Opportunities for improvement identified in the reviews conclude with corrective actions to be taken
- Records of the reviews include attendees and information discussed
- Information provided from the reviews is consistent regarding adequacy
- Identified problems and their corrective actions are clearly and consistently stated and followed for completion

Conclusion and Key Messages

Management review when conducted periodically at set frequencies, allows senior/top management to confirm with confidence the status of effectiveness of their management system and how well it is working in meeting the organization's planned results. As such the CNSC's key expectations from the licensees are:

- A review of the effectiveness of the management system is routinely conducted by senior/top management
- Data inputs for management review are complete, analyzed and correlated with the outputs to achieve the planned results
- Licensees top management review the data and challenge the conclusions as required
- Decisions are taken and communicated in a timely manner to improve the management system and the business objectives





Thank You !



