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The Management System Integration, Graded Approach and Documentation

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
IAEA - Department of Nuclear Safety & Security

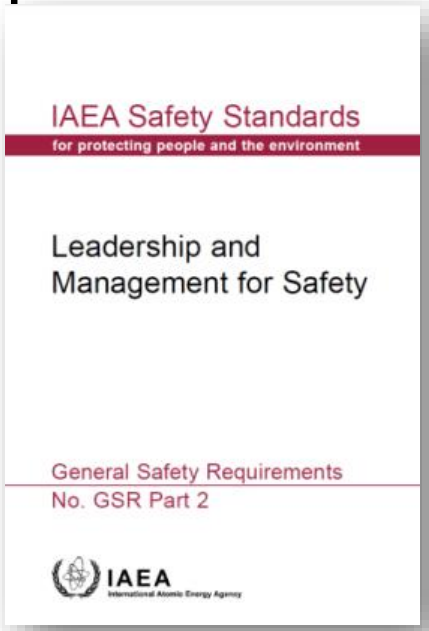
Learning objectives

This lecture is aiming to introduce the relevant requirements and recommendations applicable to

- Integration of management systems
- Application of a graded approach
- Documentation of the management system

Content

1. Introduction
2. Requirement 6: Integration of the management system
3. Requirement 7: Application of the graded approach to the management system
4. Requirement 8: Documentation of the management system
5. Key messages



1. Introduction

- Requirement 6: Integration of the management system

  The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised.

- Requirement 7: Application of the graded approach to the management system

  The management system shall be developed and applied using a graded approach.

- Requirement 8: Documentation of the management system

  The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use.

1. Introduction

The following aspects will be addressed

- Integration means a real integration of the all the requirements in the processes, also those derived from the expectation of the interested parties
- Objective of grading the application of the management system requirements is to enable that valuable resources and attention to be targeted at the activities of greater significance
- What should be documented and how

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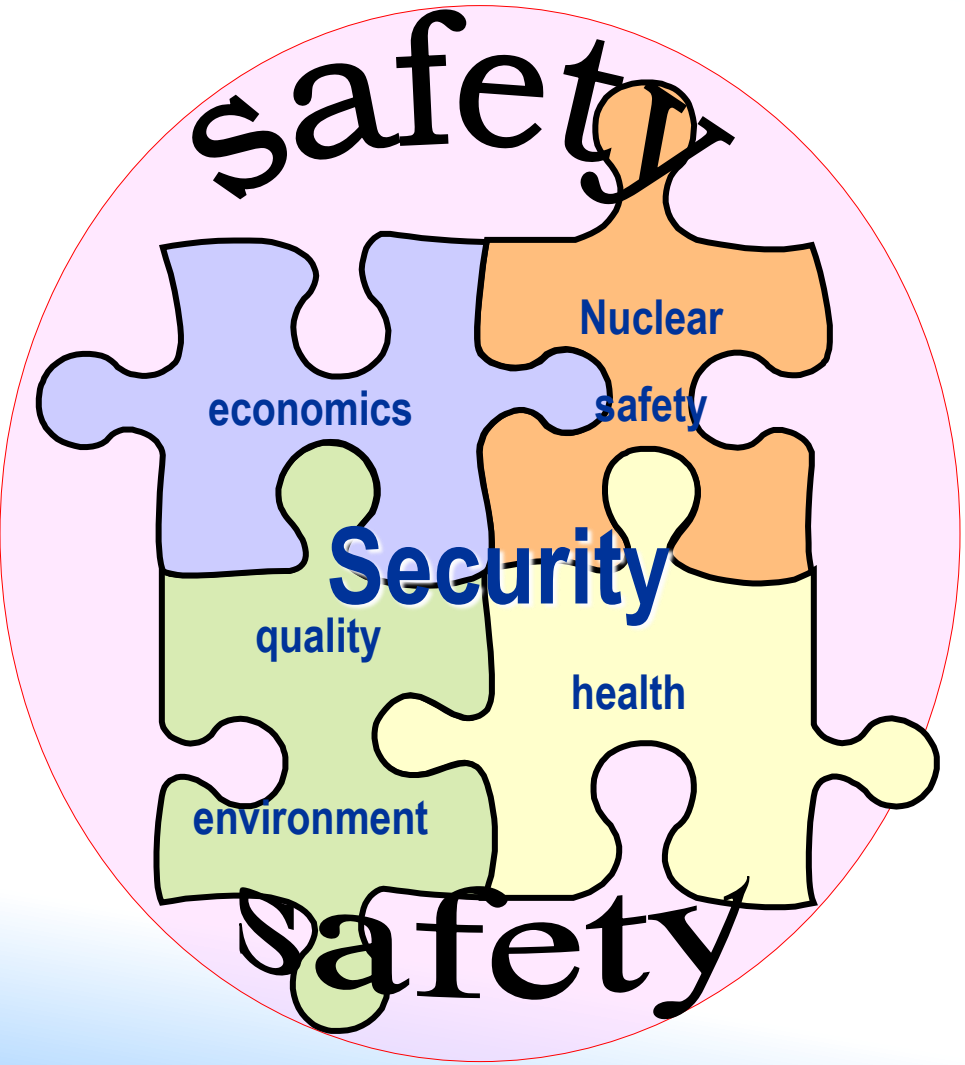
Integration of the management system

2. Integration of the management system

- The management system has to integrate all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and security; and so that neither safety nor security is compromised by the need to meet other requirements or demands

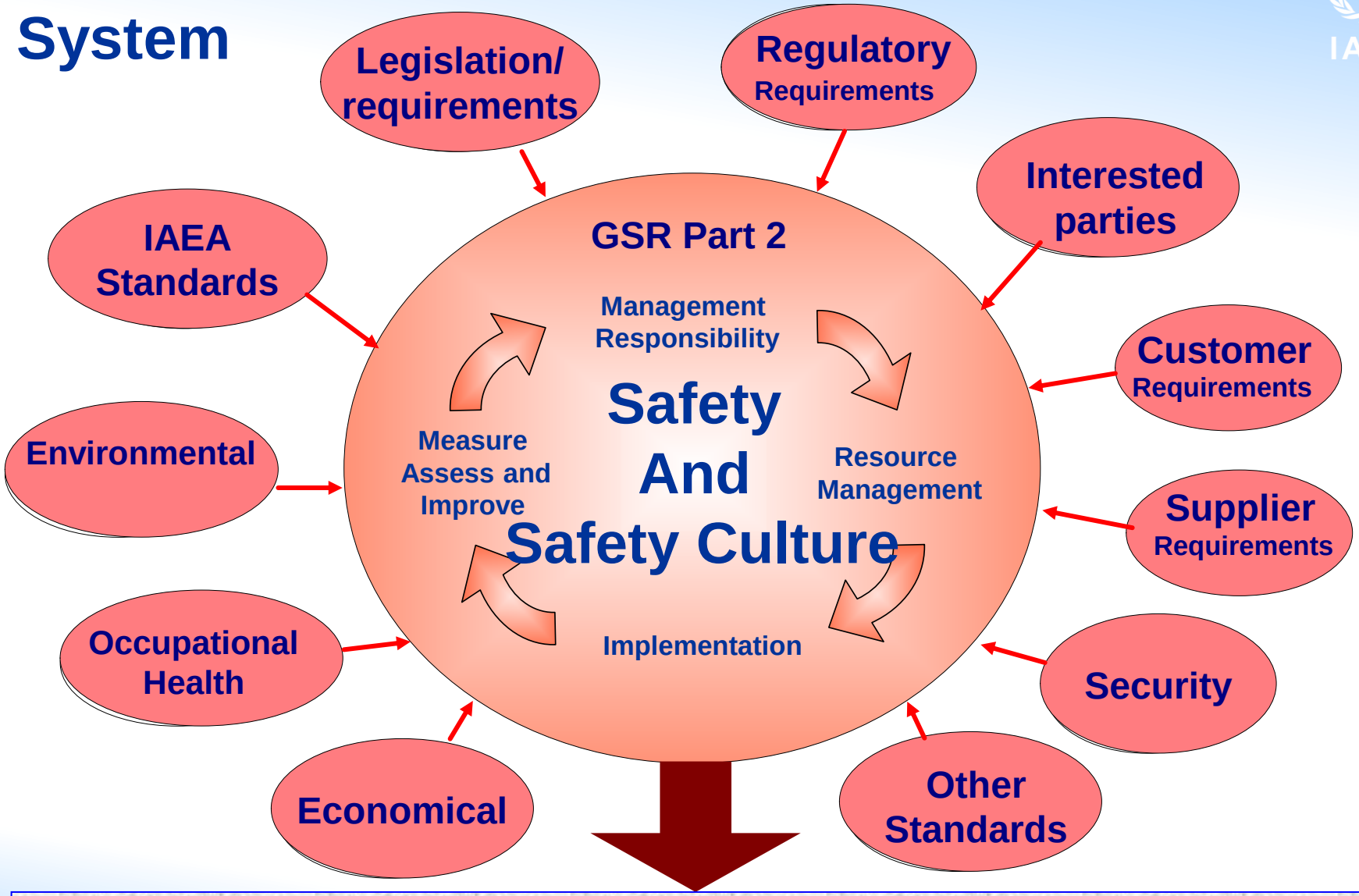
- Safety measures and security measures must be designed and applied in an integrated manner

Integrated Management Systems



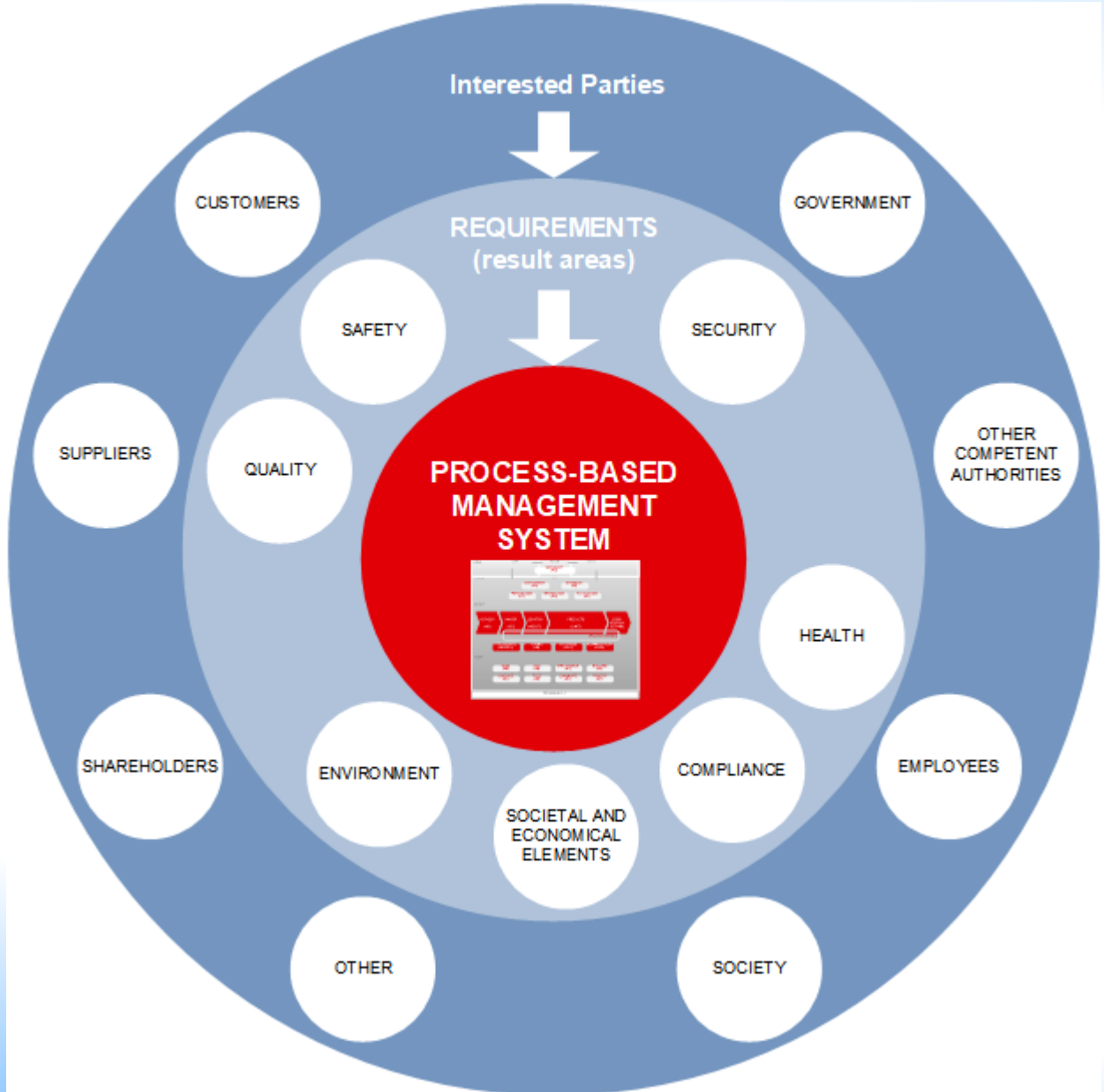
- All the requirements for a process have to be identified and applied in the related process
- All interaction with other processes have to be identified and integrated in the related process
- All to ensure that **safety** is not compromised

IAEA GSR Part 2: Integrated Management System



TO ENSURE THAT SAFTY IS NOT JEARPORDISED

Integration of expectations of Interested Parties



The expectations of interested parties shall be considered Translated into requirements and interactions with the processes identified The aim is enhancing the satisfaction of interested parties But at the same time it must be ensured that safety is not compromised.

Integration of requirements

- For proper integration of the requirements a gap analyses matrix have to be developed
  - For every process the relevant requirements should be identified
  - Identified whether s the requirement already covered
  - Description of the gap
  - This overview is to be used in the development of a process

Gap analysis matrix				
Requirements for the future state process	Existing process situation	How the requirements are covered, including reference to any documents.	Requirement status • Covered • Partially • Not covered	Description of gaps identified

FIG. 9. Example of a gap analysis framework in table format.

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Grading the application of the Management System

3. Grading the application of IMS requirements

4.15. The criteria used to grade the development and application of the management system shall be documented in the management system. The following shall be taken into account:

a) The safety significance and complexity of the organization, operation of the facility or conduct of the activity;

b) The hazards and the magnitude of the potential impacts (risks) associated with the safety, health, environmental, security, quality and economic elements of each facility or activity [16, 24–26];

c) The possible consequences for safety if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out.

Requirement applies to both: Licensee and Regulatory body's Management system.

- It should duly consider for grading processes: Review and Assessment, Licensing process, Inspection, Enforcement…

3. Grading the application of IMS requirements

- Objective of grading the application of the management system requirements is to enable that valuable resources and attention to be targeted at the activities of greater significance
- The proper use of graded approach can result in minimizing resources while improving efficiency and safety
- A **graded approach** applies IMS requirements to a process or activity commensurate with
  - its relative importance, complexity, variability, maturity
  - potential impact on safety, health, environmental, security, quality and societal and economics elements
  - the possible consequences if the product fails or if the activity is carried out incorrectly.

3. Grading the application of IMS requirements

- Examples of Graded Approach
  - Changing oil filters of a car engine or airplane engine
  - Change water cleaning filters for secondary system or primary water purification system
  - Check water reservoir of car windscreen
  - Maintenance of a pump for drinking water or for fire fighting equipment
  - Checklist or instruction for experienced senior or junior operator/technician
  - Checklist for reactor start or checklist for holidays
  - Access control for archive with info material for public and archive with security measures

3. Grading the application of IMS requirements

- **Examples, graded approach applies to the following regulatory activities** (Refer to GSR Part 1)
  - Requirement 26: Review and assessment
  - Requirement 29: Inspections of activities
    - frequency of inspections and the areas and programmes to be inspected, determined in accordance with a graded approach
  - Requirement 31: Regulatory body's response to a non-compliance with regulatory requirements or with any conditions specified in the authorization
    - to be commensurate with the significance for safety of the non-compliance

3. Grading the application of IMS requirements

- The regulatory body should develop and implement a structured approach to determining how the management system requirements should be applied to products and activities.
- Consequently, a methodology for grading that ensures that all staff applies this common sense approach in a uniform manner
- Provisions to be embedded in the management system
  - to allocate properly the resources of the regulatory body among its different tasks according

3. Grading the application of IMS requirements

- For the document and records management, examples of controls that could be graded:
  - Different staff expertise's for preparation of documents and records (“technical”, political, lawyers, etc.)
  - Level of review and approval to which documents are subjected
  - Document distribution (to whom and how)
  - Need to archive superseded documents
  - Need to categorize, register, index, retrieve and store document records;
  - Retention time of records

3. Grading the application of IMS requirements

Examples of topics to be considered for grading MS

Training

- Training/retraining programme
- Review, approval and authorization of training programmes

- Assessment, measuring Improvement
  - Audit/inspection programme based on
    - Audit and inspection results
    - Outcome of the management review
    - Fault reports, operational feedback
    - Near miss reports, precursor events, incidents

Examples of topics to be considered for grading MS

- What are the consequences of loosing knowledge for
  - Development of regulations
  - Development of licenses
  - Nuclear knowledge
  - Knowledge of national laws, acts for environmental protection, security, environmental control, occupational health, etc. and
  - Personnel dose data, Chemical exposure data
- Potential hazard in case of security breach for staff, public, environment

Examples of grading aspects during oversight

Organizational Structure

- Complexity of organizational structures and appropriate levels of management and supervision within the organization implemented?

Operations

- Assessment and inspection of operations, incl. procedures and instructions

Documentation

- Assessment and authorization of formal documents
- Review and audit of management system documentation

Training

- Review, authorization and involvement of training programmes
- Follow up on near miss reports, precursor events, incidents
- Enforcement after violations

Additional information for grading of oversight activities

Insight in results and trends in following subjects

- Management reviews
- Safety culture
- Malfunctions/operational disturbances
- (potential) unsafe situations/ near misses
- incidents
- inspections of regulatory body
- IAEA review services
- Results of audits
- Complaints and non-conformities
- Status of outstanding preventive and corrective measures

Classes of event reports

- First quality grade: Events associated with improper work performance resulted in severe radioactive releases and accidents that requires reporting to the regulatory body.
- Second quality grade: Events associated with improper work performance that resulted in non-compliance with the requirements set, serious radiological risk, serious injuries of people and economic damage that requires reporting to the regulatory body.
- Third quality grade: Events associated with improper work performance that resulted in minor economic damage and minor risk of radiological hazard.
- Fourth quality grade: Events associated with improper work performance not included in the first three quality grades and not influencing the reliability and safety of the plant, personnel, population and environment.

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Documentation of the Management System

4. Documentation of the Management System

The management system documentation should reflect the characteristics of the regulatory body, its activities and the complexities of the regulatory processes and their interactions.

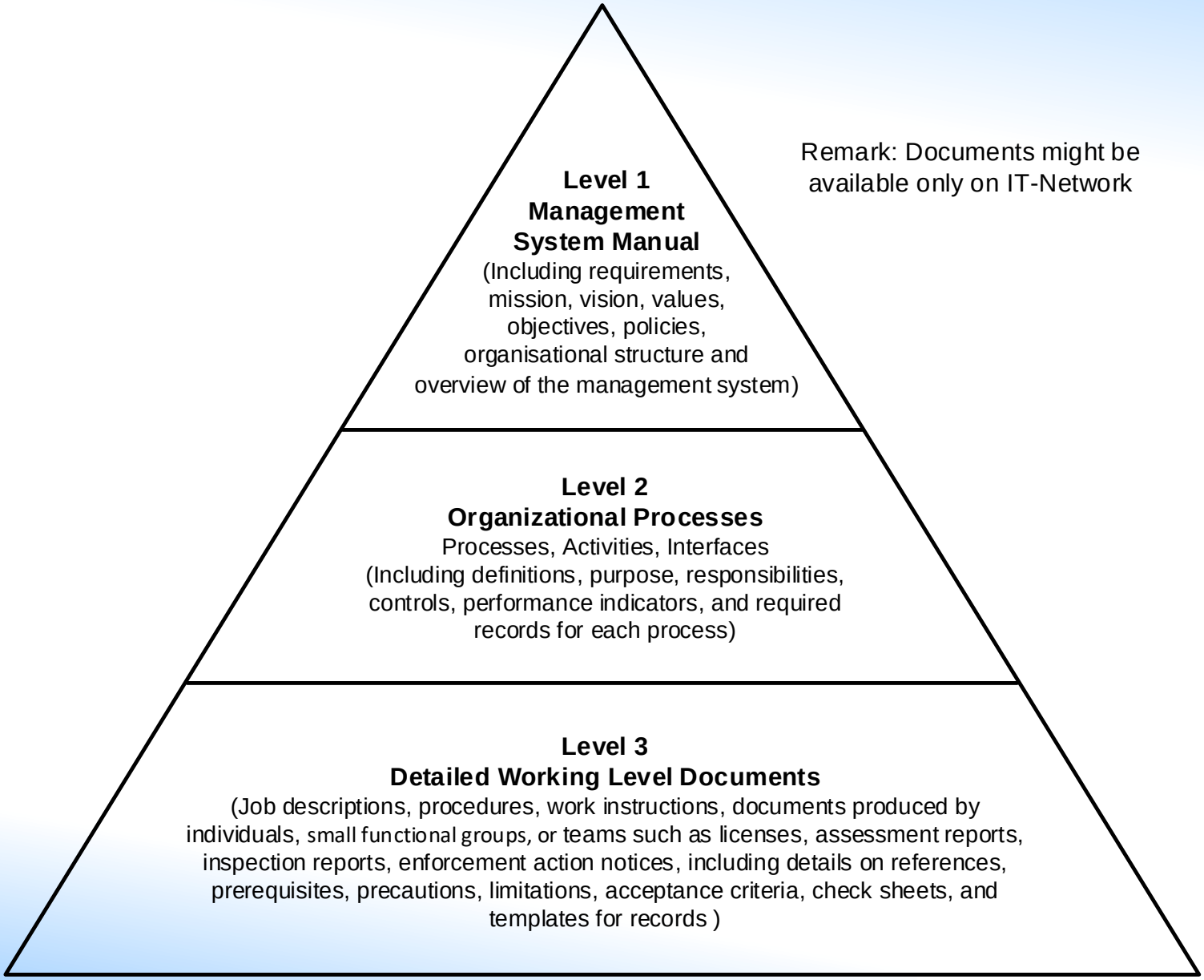
- The management system shall be documented.
- The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use.

4. Documentation of the Management System

The documentation of the management system shall include as a minimum:

- policy statements on values and behavioural expectations
- the fundamental safety objective
- description of the organization and its structure
- description of the responsibilities and accountabilities
- the levels of authority, including all interactions of those managing, performing and assessing work
- the processes
- description of the interactions with external organizations and with interested parties
- Methodology of the graded approach to be applied

Example of documentation structure



Remark: Documents might be available only on IT-Network

Control of documents

- The documents shall be reviewed, revised and approved by competent persons and at the appropriate level
- Also revisions to documents shall be controlled, reviewed and recorded.
- Revised documents shall be subject to the same level of approval as the initial documents.
- All documents shall be readable, complete, identifiable and easily retrievable.
- Retention times of documents and records shall be established to be consistent with the statutory requirements and with the obligations for knowledge management of the organization.
- The media used for records shall be such as to ensure that the records are readable for the duration of the specified retention times

NRG-OD 3.10: ARCHIVE AND TERMLIST Revision date: ***21.04.2011***

Approved Manager QSE :

CENTRAL DOCUMENTS	Expire period [1)]	Responsible
Policy	10 year	Dir. Secretariat
Business plan	3 year	Dir. Secretariat
Minutes Management Team	3 year	Secretariate
Personal dose data	30 year [2) 3)]	Dosimetriedienst RE
Organization sheet NRG	3 year	***Manager QSE***
Job descriptions	3 year	Human Resources
Waste disposal data	10 year	Manager QSE
Licensing documentation	10 year [3)]	Manager QSE
Near miss and incident reports	10 year [3)]	Manager QSE
Correspondence with competent authorities	10 year [3)]	Manager QSE
Radiological work permits	1 year	QSE
Transport documents RA material	1 year	QSE
Data of radio active releases	10 year	QSE

1) Years after dismantling of installation

2) Until age of 75 but at least 30 years after determination of employment

3) *Legislation requirement*

It is the responsibility of the receiver to incorporate the new version and to destroy the old version.

Key messages

- Integration means real integration of all the requirements in the processes, also those derived from the expectation of the interested parties
- Grading the application of the management system requirements enables that valuable resources and attention can be targeted at the activities of greater significance
- Grading will bring efficiency in the organization without jeopardizing safety
- Development, control and proper storage of management system documentation is essential and documentation should be easy to use at the place they are needed

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Thank you!