



# PREDIS

# QUALITY MANAGEMENT SYSTEM

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DOMAIN INSIGHT TRAINING

22 MAY 2024

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945098.

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# **PREDIS Quality Management System, Goals**

**Within Radioactive Waste Management (RWM) crucial frameworks designed to ensure that the processes, procedures, and responsibilities for achieving quality objectives are defined, implemented, and maintained.**

**Role of QMS in RWM to safeguard the environment and public health by ensuring that radioactive waste is managed in a manner that meets international standards and practices**



# **PREDIS Quality Management System, Goals**

**Focused in PREDIS, Quality Management System inside RWM establishes the methodology and procedures to guaranty that processing, transport, disposal/storage, for the approved wasteforms, keep the compliance with applicable WAC.**

**Once the implementation of WAC has been carried out with the development of the Waste Acceptance Process, Quality Assurance must design the controls that assure the proper way of proceeding and the fulfillment of WAC.**



# **PREDIS Quality Management System, Goals**

**The needed structure of actions, methods and procedures that guarantee the maintenance and optimization of one approved process, in relation to the Manufacturing and Acceptance of radioactive Items (Packages, Casks, Disposal Units, Large Components) for Final Disposal – Interim Storage.**

**A formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.**





# PREDIS Quality Management System, Goals

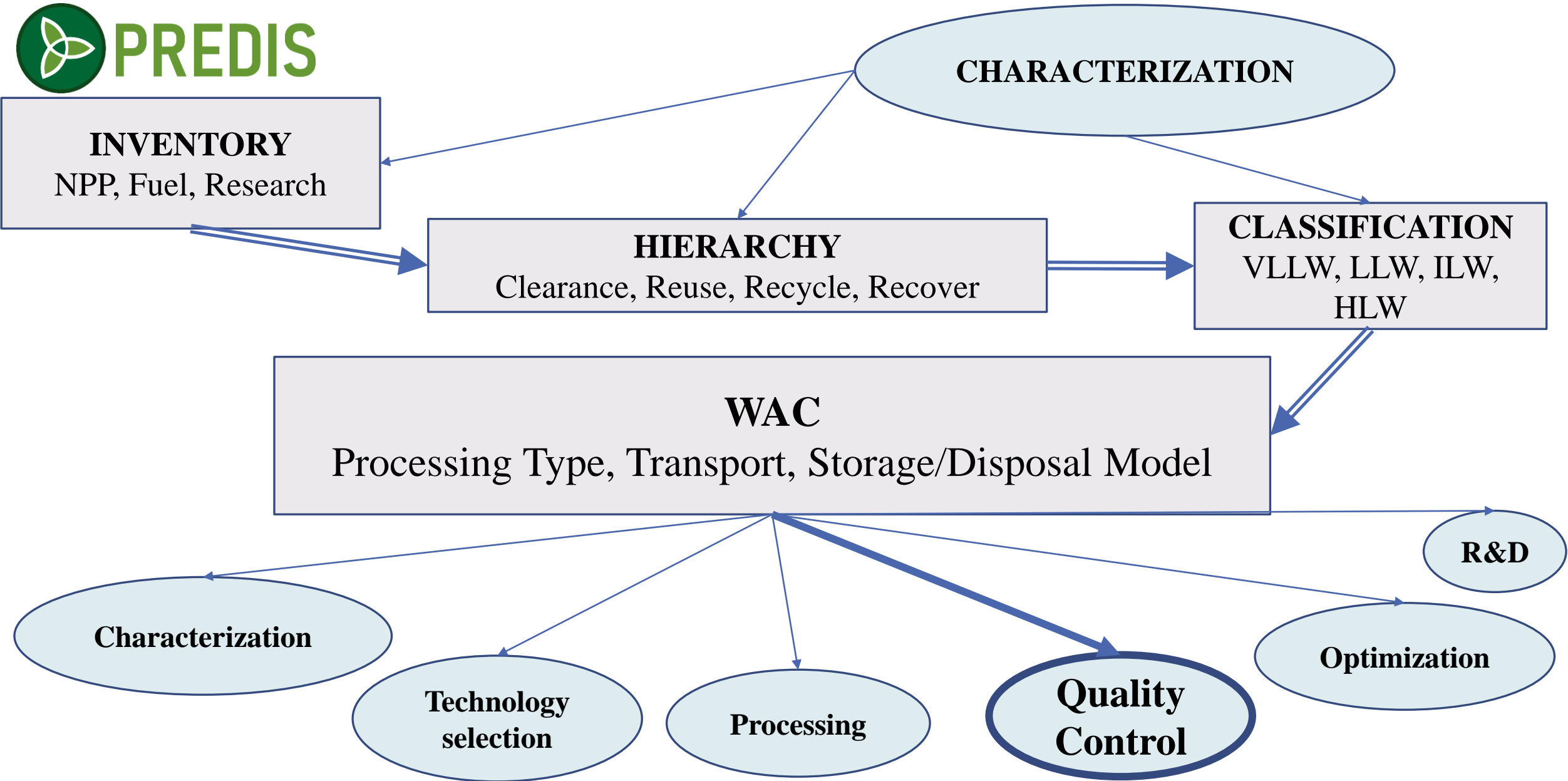
Domain Goal	
Domain Activities	
Phase 1: Planning and Programme Initiation	Grading nuclear activities in relation to safety. Processing/Storage/Disposal QMS
Phase 2: Program Implementation	Defining methodologies, procedures, controls to guaraty safety
Phases 3–4: Program Operation/Optimisation and Closure	knowledge preservation (record keeping,...), knowledge transfer in the overall RWM, Resolution of Non-Conformities arising from operations. Feedback to improve processes.



# PREDIS QMS LEGISLATION

- ANSI N45.2 Quality assurance program requirements for nuclear facilities
- ISO 19443:2022 Quality management systems - Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS).
- GS-R-3 Safety Requirements Series the Management System for Facilities and Activities.
- GSR Part 1: "General Safety Requirements: Safety Fundamentals,"
- 10CFR21 Reporting of defects and Noncompliance.
- Appendix B 10 CFR 50 Quality Assurance for Nuclear Power Plants.
- IAEA-TECDOC-1335: "Guidance for the Application of an Assessment Methodology for Innovative Nuclear Energy Systems"

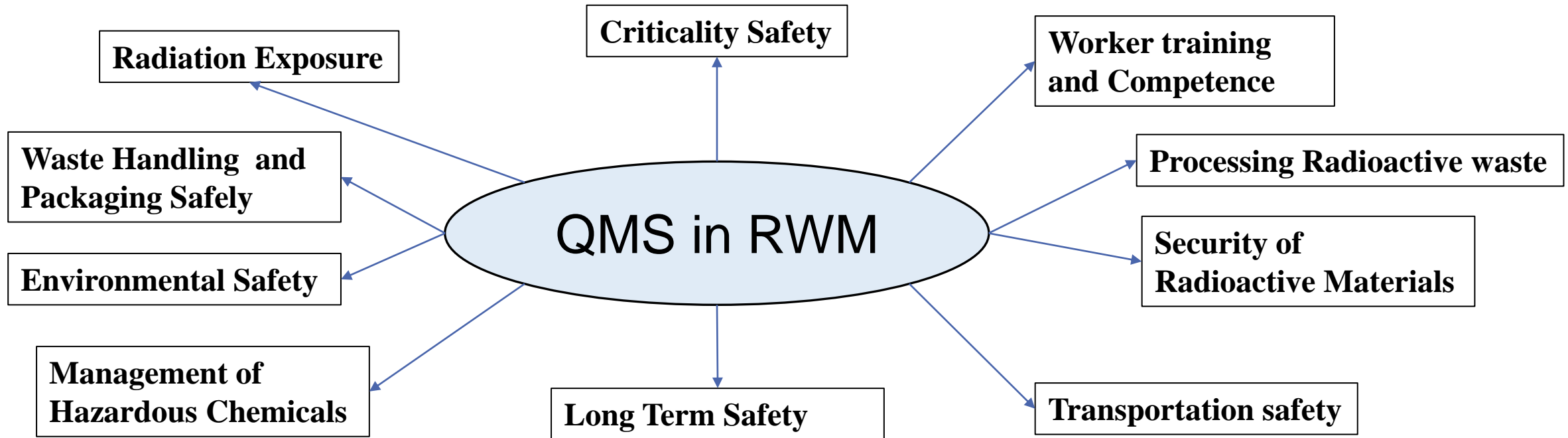






# QMS, General Standpoint

## Generic safety issues for QUALITY MANAGEMENT SYSTEM



**QMS helps ensure the protection of personnel, the public, and the environmen**

# PREDIS QMS PLANNING

- The nuclear QMS activities are defined in two levels:
  - Important to safety:
    - Are those classified as Safety (also called safety-related).
    - Those classified as Safety Relevant.
  - Not important to safety.

## Graduated Quality Assurance Program into 3 levels

- Level I, activities considered Security or Safety Related, as well as the activities directed to them, will be classified as.
- Level II, those activities considered Safety Relevant, as well as the activities and processes directed to them.
- Level III, activities, as well as the processes associated with them, which, without complying with the criteria to be classified as I or II, but are necessary to ensure quality in the process.



Important to safety:

- To which credit is given in analysis of internal or external events or severe conditions to ensure the primary safety functions or safety objective.
- Those whose purpose by design is to avoid exceeding the established dose limits for workers or members of the public during the normal operation of the plant.
- Those that have been shown to have a significant impact on the risk of the installation.
- Those whose failure could prevent the operation of the systems defined as security or related to security.



# PREDIS QMS PLANNING

- Waste treatment and conditioning are critical stages in RWM. Prepare the waste for safe disposal, storage, or recycling.
- Quality objectives in waste treatment and conditioning must be tailored to the specific types of radioactive waste (e.g., low-level, intermediate-level, high-level, or spent fuel)..
- QMS facilitates the optimization of waste treatment and conditioning processes, ensuring they are both efficient and effective. Selection of optimal waste forms, treatment methods, and conditioning materials that minimize the waste volume, meet safety and durability criteria for long-term waste disposal or storage.
- QMS to verify the fulfillment of WAC in the Storage/Disposal for one or several of the entities like:
  - Packages.
  - Disposal Units.
  - Large Items/Components.
  - Casks.



# PREDIS QMS IMPLEMENTATION IN PREDIS

Every final produced package must fulfill all the applicable WAC regarding the involved wasteform inside the defined WAS.

How to control whether the provided data are valid is a question of Quality Assurance. Therefore, a quality system must be developed to guaranty the compliance of the established requirements:

- Hard way, QMS by measuring waste/packages (Casks, Large items, etc.).
- Smart way, QMS by controlling Processes.
- A mixture of both, some data are verified waste/package by waste/package and other data are verified Process by Process. This is the common approach normally developed.



# PREDIS QMS IMPLEMENTATION IN PREDIS

Quality Management System is mainly focused to validate the followings:

- **Generic:** Identification, Tracking, Codification, Package Dimensions, Weight, Activity Classification, Historical (Legacy)/ Non-Historical.
- **Radiological:** Isotopic Composition, Dose Rate, Surface contamination, Difficult to Measure Isotopes/Scaling Factors. Fissile material content. Heterogeneity.
- **Chemical:** Pyrophoric and explosive material, Chemical Toxicity, Leaching accelerators, Complexing agents, Free liquids, Organic liquids, Corrosion.
- **Containment Capability/Release Rate:** Leaching, Diffusion.
- **Physical:** Heat Release, Package Volume Optimisation, Gas Release.
- **Biological:** Waste degradation, Gas production.
- **Mechanical:** Compression, traction, Compression after water immersion, Mechanical resistance after thermal cycles.



# PREDIS QMS IMPLEMENTATION IN PREDIS

Waste/Package by Waste/Package: for small nuclear market/producers where the number of waste/packages to control is small enough. On the other hand, for intermediate or large nuclear market, it is not a feasible way to proceed. Take for example into consideration that there are around 200.000 Packages disposed at El Cabril Disposal Centre.

Process by Process: to also control every waste/package by controlling the process of production that considers all the WAC. Package Specification, PS, the producer describes all the aspect/properties to check for a WasteForm. Describing the waste stream, treatment, condition, characterization, etc. Approval process is established that assures compliance with the required criteria



# PREDIS QMS IMPLEMENTATION IN PREDIS

- Two kinds of Quality Controls could be implemented:
  - On-Site, Off-Site Controls, O&OC.
  - Laboratory Controls, LC.

O&OC have the finality of checking all the involved aspects of the producer package streams by means of surveys that partially cover some of the criteria, trying to perform several of these surveys to cover the whole process. Examples of these Controls

LC have the finality of measuring WAC properties to data validation/verification.





# PREDIS QMS IMPLEMENTATION IN PREDIS

## O&OC:

- Off-Site Documentation Survey: inspection of all the procedures/documentation associated to all PS the producer has, just to notice of new revisions and the scope of that revisions in relation to the approved process.
- On Site Means Control: Inspection performed before the PS approval, verifying that there are the proper means to produce the package nature involved in PS.
- On site Process Survey: inspection of some part or the whole process of the package manufacturing to check the means, condition materials, etc., indicated in the PS.
- Off Site Waste survey: inspection focused on one PS and several manufactured packages, checking all data and linked forms, analyzing their agreement to the approved PS and WAC.
- On site Activity Survey: Inspection with measuring devices to compare the producer assigned activity with the measured one.
- Off Site Activity survey: Inspection of packages activity data sheet.



# PREDIS QMS IMPLEMENTATION IN PREDIS

## LC:

- Non-Destructive Laboratory Control: Measurements of basic data like mass, dose rate, package integrity, Gamma spectrometry, etc. to verify the WAC.
- Destructive Laboratory Control: Measurements of difficult to measure radionuclides, core sampling for mechanical tests, leaching, etc

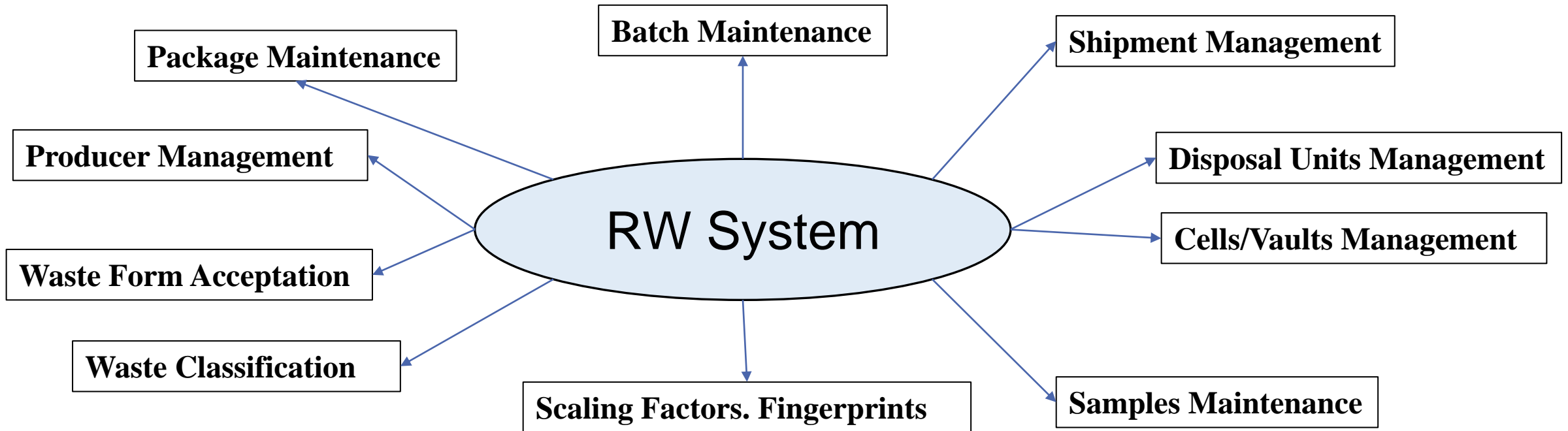


# PREDIS QMS OPERATION IN PREDIS

- Once controls are carried out, a data recording along with management of non-conformities must be analysed to improve the whole waste acceptance process.
- All required data linked to package properties/aspects must be recorded in a System that officially allow their tracking. Additionally final place in disposal or temporal place in storage must be also tracked.
- Management System must be under control applying the current quality tools to guaranty the correctness of data during handling in adding, consulting, saving, modification, etc.
- This System should be in communication with the Producers systems just to update the generated packages and to verify the inventory. This determines the future packages to be transported to the disposal/storage. is typically requested



## Records keeping Data Base



## Management of Producer WasteForm Documentation

# PREDIS QMS OPERATION IN PREDIS

Non-conformity management should be also deployed in the System to track any non-conformity derived from data audits, on site or off site inspections, laboratory controls:

- Non Conformity (non compliance with a mandatory requirement): corrective actions to correct the non compliance. In addition, depending on the significance for safety of the issue, it involves the definition of correction actions to eliminate the causes that originated the Non Conformity and avoid its recurrence.
- Potential Non Conformity: preventive actions to eliminated the cause that could lead to a real non conformity.
- Improvement: improvements actions for making a process or activity more efficient.
- Commitment: management and monitoring of the engagements made with the regulatory body.



<b>VLLW</b>	{	<b>Activity values reach the LLW</b> <b>HW not properly stabilized</b> <b>Free liquid</b> <b>Forbidden substances</b>
<b>LLW</b>	{	<b>Activity values reach the Level 2</b> <b>Strength values below WAC of WP level 1</b> <b>Free liquid</b> <b>Forbidden substances</b>
<b>ILW</b>	{	<b>Activity values outweigh level 2</b> <b>Strength values below WAC of WP level 2</b> <b>Leaching/diffusion values below WAC</b> <b>Free liquid</b> <b>Forbidden substances</b>



# **PREDIS NON CONFORMITIES DETECTION PROCESS**

## **❑ DURING THE WASTEFORM QUALIFICATION.**

Detected during the generic acceptance and before documental one, low number of waste packages involved.

## **❑ DURING THE QUALITY CONTROL ACCEPTANCE PROCESS.**

Detected either in On-Off site Control or in Laboratory Controls. It means that the NC is after Wasteform approval, having to analyse the waste packages affected by the non conformities detected.



# PREDIS QMS CRITICAL ISSUES I

- Regulatory Compliance: Adhering to regulatory requirements is crucial. Regulations are in place to protect human health and the environment, and compliance is necessary to avoid legal issues and ensure the safe management of radioactive waste.
- Waste Characterization: Accurate characterization of radioactive waste is essential for proper handling, packaging, and disposal. Understanding the types, quantities, and characteristics of radioactive materials is critical for selecting appropriate treatment and disposal methods.
- Safety and Security: Ensuring the safety and security of personnel, the public, and the environment is paramount. This involves implementing robust safety measures, emergency preparedness, and security protocols to prevent accidents, leaks, or unauthorized access to radioactive waste.
- Technology and Innovation: Keeping abreast of advancements in technology and innovative solutions is important for improving the efficiency and effectiveness of radioactive waste management. This includes developments in waste treatment, packaging, and disposal methods.
- Data Management: Managing vast amounts of data related to radioactive waste, including waste characterization, disposal records, and monitoring data, is crucial. Effective data management systems help in tracking and analyzing information for continuous improvement and compliance reporting.





# PREDIS QMS CRITICAL ISSUES II

- Long-Term Safety: Radioactive waste often remains hazardous for thousands of years. Planning for the long-term safety of disposal facilities, including considerations for geological stability and future human activities, is a critical issue.
- Public and Stakeholder Engagement: Involving the public and relevant stakeholders in decision-making processes is essential for gaining trust and addressing concerns. Open communication and transparency contribute to the success of radioactive waste management programs.
- International Cooperation: Radioactive waste management is often a global concern, especially when dealing with transboundary movements of waste. International collaboration and information exchange are vital for addressing challenges collectively and promoting best practices.
- Training and Education: Ensuring that personnel involved in radioactive waste management are well-trained and educated is crucial. This includes training in safety protocols, waste characterization techniques, and the latest technologies.
- Life Cycle Assessment: Conducting comprehensive life cycle assessments of radioactive waste.



# PREDIS QMS MATURITY KNOWLEDGE

- Optimization: involved processes understanding in radioactive waste management improves organizations, reduce inefficiencies, and enhance overall control.
- Risk Management: Mature knowledge allows more comprehensive understanding of potential risks associated with radioactive waste management.
- Data Accuracy and Analysis: with mature knowledge, organizations can develop robust data management systems that ensure the accuracy and reliability of information.
- Compliance Monitoring: With mature knowledge of regulatory requirements and advanced technologies for monitoring and reporting, organizations can establish effective systems to ensure compliance.
- Training and Skill Development: As knowledge matures, training programs can be designed to enhance the skills and capabilities of personnel involved in radioactive waste management.
- Integration of Best Practices: Mature knowledge allows organizations to integrate industry best practices into their QMS.
- Technology for Monitoring and Surveillance: Advanced technologies, such as real-time monitoring and surveillance systems, contribute to better control by providing instant feedback on critical parameters.



# PREDIS QMS UNCERTAINTIES

Nuclear industry is in decline due to the slow but continuous closure of NPPs. Causing the continuous disappearance of specific suppliers of the sector or the abandonment of the quality assurance programs under which they provided services or goods to the nuclear industry.

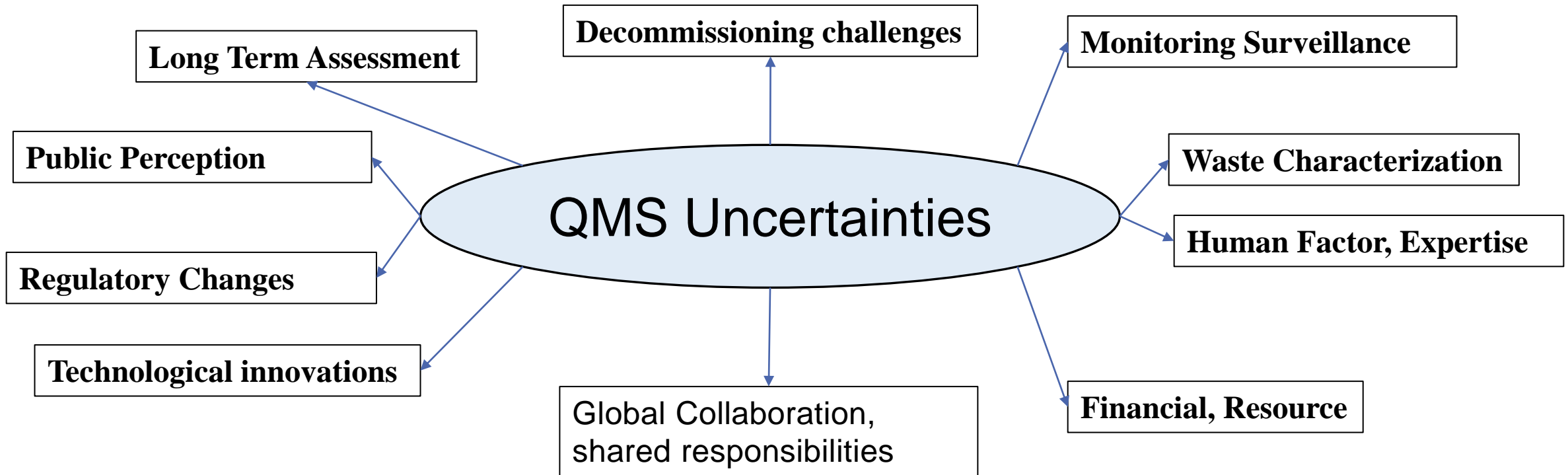
This decrease in the population of qualified suppliers for the nuclear sector can ultimately lead to:

- A shortage of services by companies that comply with the Quality Assurance standards.
- The need to adopt compensatory measures to meet the requirements of suppliers that have abandoned a nuclear quality assurance program.
- Initiate contracting processes for suppliers from countries with a large nuclear presence, with the increase in costs that this would entail.



# QMS UNCERTAINTIES

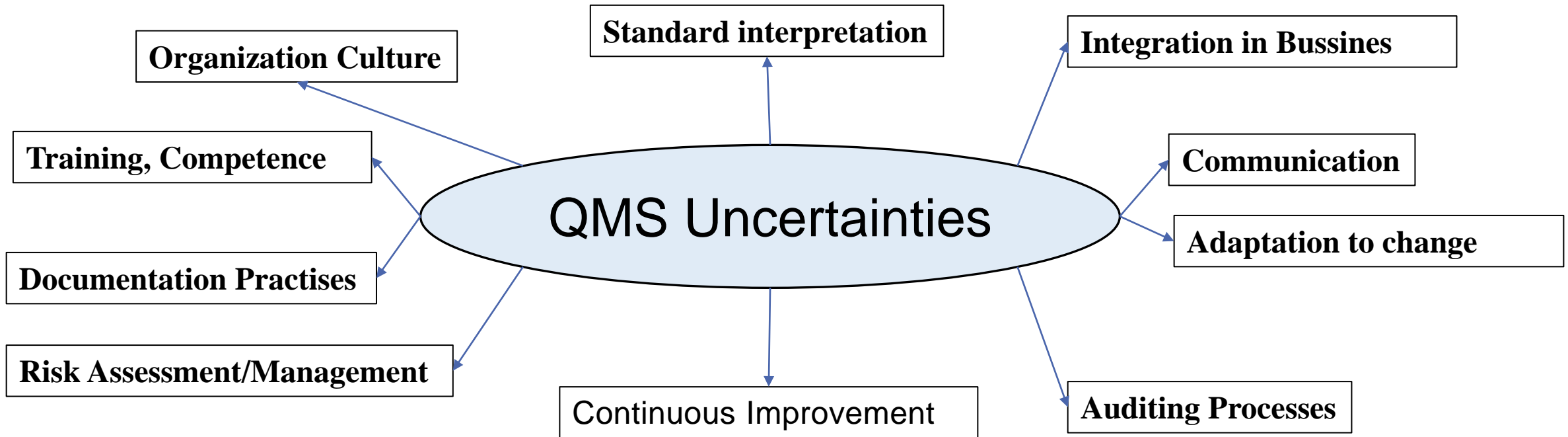
Several major uncertainties on aspects under QMS



Addressing these uncertainties requires a proactive and adaptive approach

# QMS UNCERTAINTIES

Uncertainties in the manner of applying QMS



Organizations need to foster a culture of openness, continuous learning, and adaptability.

<b>Guidance</b>
<ul style="list-style-type: none"> <li>- European Standard EN 15288 Series: The EN 15288 series of standards provides guidance on the management of facilities involved in the treatment and storage of radioactive waste. While primarily applicable in the European context, these standards can be informative for global practices.</li> <li>- ANSI/ANS-3.11-2019 - American National Standard for Management System for Nuclear Facilities: This American National Standard provides guidance on the development and implementation of a management system for nuclear facilities, including those engaged in radioactive waste management.</li> <li>- NEA-OECD Documents: The Nuclear Energy Agency (NEA) of the Organisation for Economic Co-operation and Development (OECD) publishes reports and documents related to nuclear energy, including quality management aspects. Relevant documents can be found in the "Radioactive Waste Management Committee" section.</li> </ul>
<b>Training</b>
<p><b>Training</b></p> <p><b>Communities</b></p> <ul style="list-style-type: none"> <li>- ISO: INTERNATIONAL ORGANIZATION FOR STANDARDIZATION</li> <li>- CEN: COMITÉ EUROPEO DE NORMALIZACION</li> <li>- ANSI: AMERICAN STANDARDS INSTITUTE</li> <li>- ASTM: American Society for Testing and Materials</li> <li>- IAF: INTERNATIONAL ACREDITATION GROUP</li> </ul>
<b>Active communities of practice and networks</b>
<p><b>IAEA: IPN, Labonet, Disponet.</b></p> <p><b>OCDE-NEA: Radioactive Waste Management Committee (RWMC)</b></p>





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**THANK YOU VERY MUCH  
FOR YOUR ATTENTION**

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