SHINE EU Management System

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Revision History

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Abbreviations

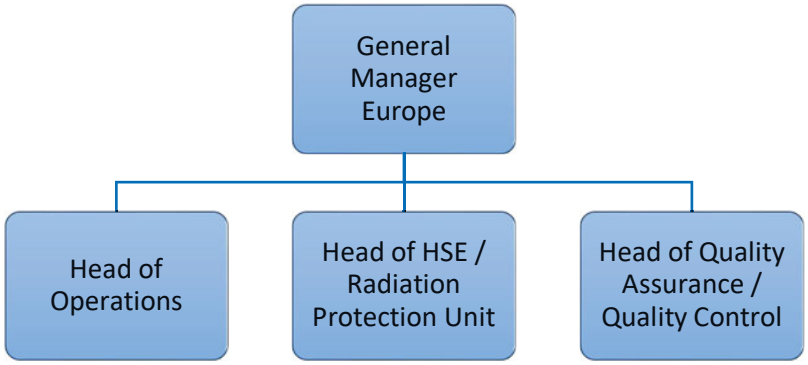
Abbreviation	Description
Bbs	Besluit basisveiligheidsnormen stralingsbescherming (Dutch law)
EU	Europe
KeW	Kernergiewet (Dutch law)
QC	Quality Control
Lu	Lutetium
MS	Management System
RPU	Radiation Protection Unit

1 General

SHINE EU maintains a management system that integrates quality, safety, security, and environmental considerations relevant to its operations. The company commits to designing, procuring, operating, and maintaining the SHINE EU facility in a manner that ensures the health and safety of the public and workers while protecting the environment. Operations will be conducted in compliance with Article 29 of the Kernenergiewet (KeW) [1] and other applicable regulatory requirements.
SHINE EU produces radioisotopes in a controlled environment, ensuring that safety and quality are embedded in daily operations. Management recognizes that achieving high standards in quality, safety, and environmental performance is critical to the company's success and is actively engaged in their implementation. Every employee is responsible for maintaining quality standards, which are not achieved solely through inspections but through knowledge, skills, experience, and training. The management system (MS) ensures cost-effective, efficient, and safe production while meeting regulatory requirements.

1.1 Management System Organization Structure

The principle of the overall organizational structure of SHINE EU, for ensuring management system implementation, is the following:



1.2 Quality Assurance Organizational Independence

To maintain objectivity, independence shall be ensured between the organizational units responsible for performing work or providing services and those overseeing quality assurance and quality control.

2 Description of the Management System

According to Bbs [2] article 4.2, records of sources should be housed in the management system. Moreover according to Bbs [2] article 6.2 point 6, " the entrepreneur is obliged to introduce and maintain a system for the recording and analysing radiation incidents, accidents or radiological

Emergencies" ("is de ondernemer verplicht tot het invoeren en in werking houden van een systeem voor het registreren en analyseren van stralingsincidenten, ongevallen of radiologische noodsituaties").

In addition to those requirements, SHINE EU will also keep track of:

- Deviations, corrective and preventive actions
- Document control
- Change control
- Training of qualified personnel
- Periodic audits and reviews

The following sections outline the specific requirements of SHINE EU's MS linked to the application under article 29 of KeW.

2.1 Non-conformities including a system for recording and analyzing radiation incidents, accidents or radiological emergencies

In compliance with Article 29 of the KeW [1], a system for recording and analyzing radiation incidents, accidents, and radiological emergencies will be integrated into the company's management system. This system ensures that any non-conformities related to radiation safety are identified, documented, evaluated, and addressed in a structured manner.

Key Elements of the System:

1. **Incident Identification & Classification:**
    - All radiation-related events will be classified based on severity, from minor deviations to significant incidents.
2. **Documentation & Reporting:**
    - A centralized database will be maintained to log all radiation incidents, capturing key details such as date, location, personnel involved, nature of the incident, and potential consequences.
    - Incident reports will be generated, reviewed by the radiation protection unit (RPU), and, when required, submitted to relevant regulatory authorities.
3. **Analysis & Investigation:**
    - Root cause analysis will be conducted for each recorded significant incident to determine contributing factors and preventive measures.
4. **Corrective & Preventive Actions:**
    - Based on findings, corrective measures (e.g., equipment adjustments, training enhancements, procedural changes) will be implemented to mitigate risks.

5. **Segregation & Control of Non-Conforming Items:**
    - Any materials, equipment, or processes found to be non-compliant will be immediately identified, isolated, and evaluated.
    - A decision-making process will determine whether the item can be repaired, reworked, or must be removed from use.
6. **Regulatory Compliance & Continuous Improvement:**
    - The system will align with national regulations.
    - Periodic reviews and audits will be conducted to refine procedures and enhance radiation safety management.

2.2 Radiation Source Records

In accordance with Bbs [2] Article 4.2, SHINE EU shall maintain a system for recording and managing all radiation sources within its facility. This system shall ensure:

1. **Accurate Inventory Tracking**
    - A centralized database will store records for each radiation source, including:
        - Unique identifier (serial or batch number, type, and isotope)
        - Activity levels and decay information
        - Location and storage conditions
        - Responsible personnel
2. **Secure Storage & Handling Procedures**
    - Radiation sources will be stored in designated, controlled areas with appropriate shielding and access restrictions.
3. **Recordkeeping & Retention**
    - All source records will be maintained for the legally required period and be available for regulatory review.
4. **Regulatory Compliance & Reporting**
    - The Radiation Protection Unit (RPU) will ensure timely updates and compliance with reporting obligations to relevant authorities.

2.3 Deviations, corrective and preventive actions

SHINE EU shall ensure that conditions adverse to quality, safety, and regulatory compliance are identified, evaluated, and addressed promptly. Corrective and preventive actions shall be implemented in accordance with documented procedures.

1. Corrective Actions

- Any deviation, non-conformance, or identified deficiency shall be documented and assessed to determine its cause.
- Corrective actions will be taken to eliminate the cause and prevent recurrence.
- For significant conditions adverse to quality or safety, a root cause analysis shall be performed, and corrective measures shall be verified for effectiveness.

2. Preventive Actions

- SHINE EU shall proactively identify potential risks and non-conformities before they occur through:
    - Trend analysis of operational data, incidents, and audit findings.
    - Regular inspections and monitoring to detect early signs of degradation or failure.
- Preventive actions shall be documented and implemented to mitigate risks before they result in non-compliance or safety concerns.
- Training programs shall be used to prevent recurring human errors by reinforcing best practices.

3. Effectiveness Review

- All corrective and preventive actions shall be tracked, reviewed, and periodically assessed to confirm their long-term effectiveness.

2.4 Document control

All activities affecting quality shall be performed according to documented procedures, instructions, or drawings appropriate to the circumstances. These documents shall:

- Include or reference quantitative or qualitative acceptance criteria for satisfactory performance.
- Be developed to prescribe expectations, define work sequences, and ensure consistency.
- Be readily accessible to internal and external stakeholders performing or overseeing work.

2.5 Change control

SHINE EU shall establish procedures to manage modifications to quality control, manufacturing processes, safety measures, and equipment relevant to the facility's compliance with Article 29 of the KeW. The control measures shall include:

- Documentation and justification of operational changes.
- Verification that changes align with regulatory requirements and operational safety goals.
- Review of significant changes and corresponding updates to procedures and control measures.

2.6 Training

Regulatory requirements mandate that personnel is qualified through education, training, and experience. SHINE EU will ensure that:

- Employees and contractors have access to relevant qualification requirements and training resources.
- Training records are maintained for regulatory review and internal assessments.

2.7 Periodic Audits and Reviews

Periodic audits and reviews shall be conducted to assess the effectiveness of the management system and ensure ongoing compliance with regulatory requirements. These audits will:

- Evaluate adherence to radiation safety procedures and operational protocols.
- Identify areas for improvement and recommend corrective actions.
- Ensure that records and documentation are up-to-date and accurate.
- Be carried out by independent internal or external auditors to maintain objectivity and thoroughness.

3 References

[1] Dutch Law, “Kernenergiewet.” [Online]. Available: https://wetten.overheid.nl/BWBR0002402/2024-07-01/0

[2] Dutch law, “Besluit basisveiligheidsnormen stralingsbescherming.” Accessed: Mar. 13, 2025. [Online]. Available: wetten.nl - Regeling - Besluit basisveiligheidsnormen stralingsbescherming - BWBR0040179