

Report

Radioactive Waste Treatment and Conditioning Safety Reference Levels

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**Report of the Working Group on Waste and Decommissioning
(WGWD)**

October 2016

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Executive Summary

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The Western European Nuclear Regulators' Association (WENRA) is an international body made up of the Heads and senior staff members of Nuclear Regulatory Authorities of European countries with nuclear power plants. The main objectives of WENRA are to develop a common approach to nuclear safety, to provide an independent capability to examine nuclear safety and to provide a network for chief nuclear safety regulators in Europe to exchange experience and discuss significant safety issues.

To accomplish these tasks two working groups within the WENRA have been established – the Reactor Harmonisation Working Group (RHWG) and the Working Group on Waste and Decommissioning (WGWD).

This document contains the results of the work of the WGWD in the area of facility safety and the practices for the processing of radioactive waste. The objective of this report is to provide Safety Reference Levels (SRLs) for these facilities, based on good practices in the RHWG report, other WENRA reports and relevant IAEA documents (requirements, guidance, etc.).

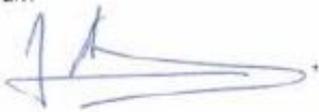
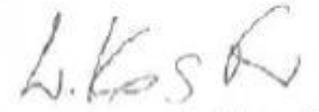
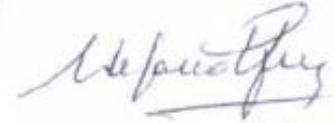
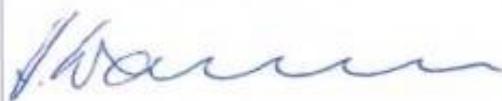
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Terms Of Reference
of the
WESTERN EUROPEAN NUCLEAR REGULATORS' ASSOCIATION
(WENRA)

1. We, the Heads of Nuclear Regulatory Authorities (signatories) of European countries with nuclear power plants:
 - drawing from the experience already gained with WENRA and noting its achievements,
 - recognizing that the current regulatory challenges in Europe lead to envisage the activities of WENRA in a broader perspective,
 - re-affirming the need for increased co-operation between us, and
 - maintaining our independence,have again revised the previous Terms of Reference of the Western European Nuclear Regulators' Association (WENRA), which were signed on 4 February 1999 and revised on 14 March 2003 and on 26 March 2010.
2. With the general aim of improving nuclear safety, has the following objectives:
 - to build and maintain a network of chief nuclear safety regulators in Europe,
 - to promote exchange of experience and learning from each others best practices,
 - to develop a harmonized approach to nuclear safety and regulation, in particular within the European Union,
 - to discuss and, where appropriate, express its opinion on significant safety and regulatory issues.
3. Decisions in the name of WENRA are taken by consensus.
4. WENRA will keep the European Union Institutions informed about its activities, and is prepared to consider requests from these institutions for advice on nuclear safety and regulatory matters.
5. Heads of the regulatory authorities (or corresponding) in other European countries, which have expressed an interest, are invited as observers to WENRA. Observers have the right to express their opinion at the WENRA meetings but can not participate in the decision making. Observers may send suitably qualified participants to the working groups.
6. WENRA will develop and maintain, when appropriate, suitable relations with regulatory authorities from other countries as well as with international organisations.
7. WENRA will ensure appropriate opportunities for stakeholders to comment on its work.

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Glossary

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For the purpose of this document, the following definitions have been adopted. Definitions identical to the IAEA Safety Glossary, 2007 Edition, are marked with an asterisk (*). For terminology not included here please also refer to the IAEA Safety Glossary.

Conditioning *

Those operations that produce a waste or spent fuel package suitable for handling, transport, storage and/or disposal. Conditioning may include the conversion of the waste to a solid waste form, enclosure of the waste in containers and, if necessary, provision of an overpack.

Facility

An installation and its associated land, buildings and equipment in which radioactive materials are produced, processed, used, handled, stored or disposed on such a scale that consideration of safety is required. Processing facilities are normally stationary facilities but there are also licensed mobile facilities.

Graded approach *

1. For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is proportionate, to the extent practicable, to the likelihood and possible consequences of, and the level of risk associated with, a loss of control.
2. An application of safety requirements that is proportionate to the characteristics of the practice or source and to the magnitude and likelihood of the exposures.

Input specification

Quantitative and/or qualitative criteria for the incoming waste to be accepted by the operator of a processing facility.

Licensee *

The legal person or organization having overall responsibility for a facility or activity (the responsible organization).

Operational limits and conditions (OLC) *

A set of rules setting forth parameter limits, the functional capability and the performance levels of equipment and personnel approved by the regulatory body for safe operation of an authorized facility.

Postulated initiating events (PIE) *

A postulated event identified in design as capable of leading to anticipated operational occurrences or accident conditions. The primary causes of postulated initiating events may be credible equipment failures and operator errors (both within and external to the facility), human induced events or natural events.

Processing

Within the framework of this report, any treatment or conditioning operation that changes the characteristics of radioactive waste.

Product

Within the framework of this report, the result of any processing step in the treatment and conditioning of radioactive waste.

Product quality

The compliance of product with the process specifications after a processing step.

Safety assessment

Assessment of all aspects of facility practice which are relevant to safety and protection of people and the environment; for a nuclear facility this includes the site, the design, construction, operation and decommissioning of a facility.

Safety assessment is a major component of the safety case.

Safety case *

A collection of arguments and evidence in support of the safety of a facility or activity. This will normally include the findings of a safety assessment and a statement of confidence in these findings.

Safety policy

A documented commitment by the licensee to a high nuclear safety performance supported by clear safety objectives and targets and a commitment of necessary resources to achieve these targets. The safety policy is issued as separate safety management document or as visible part of an integrated organization policy.

Standards

Measures of quality or suitability for a specified purpose recognized by authority or by general consent and expressed in terms of quantitative and/or qualitative rules or criteria. Examples are quality standards and safety standards.

Structures, systems and components (SSCs) *

A general term encompassing all of the elements (items) of a facility or activity which contribute to protection and safety, except human factors.

- Structures are the passive elements: buildings, vessels, shielding, etc.
- A system comprises several components, assembled in such a way as to perform a specific (active) function.
- A component is a discrete element of a system.

Treatment *

Operations intended to benefit safety and/or economy by changing the characteristics of the waste. Three basic treatment objectives are:

- volume reduction,
- removal of radionuclides from the waste, and
- change of composition.

Waste, radioactive

For the purpose of the present document, radioactive waste is material in gaseous, liquid or solid form that contains or is contaminated with radionuclides in concentrations or activities greater than clearance levels, as established by the regulatory body, and for which no further use is foreseen.

Waste characterization

Determination of the physical, chemical, biological and radiological properties of the waste to establish the need for further adjustment, treatment or conditioning, or its suitability for further handling, processing, storage or disposal.

Waste form *

Waste in its physical and chemical form after treatment and/or conditioning (resulting in a solid product) prior to packaging. The waste form is a component of the waste package.

Waste package *

The product of conditioning that includes the waste form and any container(s) and internal barriers (e.g. absorbing materials and liners), as prepared in accordance with requirements for handling, transport, storage and/or disposal.

Waste owner

The waste owner means a body having legal title to waste or spent fuel including financial liabilities. It is usually the waste and spent fuel producer.

List of Abbreviations

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EU	European Union
IAEA	International Atomic Energy Agency
OEF	Operating Experience Feedback
OLCs	Operational Limits and Conditions
PIE	Postulated Initiating Event
PSR	Periodic Safety Review
RHWG	(WENRA) Reactor Harmonization Working Group
SSCs	Structures, Systems and Components
SRL	Safety Reference Level
WAC	Waste Acceptance Criteria
WENRA	Western European Nuclear Regulators' Association
WGWD	(WENRA) Working Group on Waste and Decommissioning

Part 1

Introduction and Methodology

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1.1

Introduction

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This report is the result of a project carried out by the WENRA Working Group on Waste and Decommissioning (WGWD) between 2014 and 2016. It presents Safety Reference Levels (SRLs) for dedicated radioactive waste processing facilities as well as for radioactive waste processing activities undertaken within other nuclear facilities. The SRLs address both permanently installed systems and mobile equipment

The SRLs cannot be considered as independent European safety requirements because current legislation in WENRA member states would not allow that due to fundamental differences reflecting the historical development in European countries. The SRLs are a set of requirements against which each country is assessed, and it is the responsibility of each member country to implement actions to ensure that these requirements are met.

1.1.1 Background

WENRA, established in February 1999, is the association of the Heads of Nuclear Regulatory Authorities of European countries with at least one nuclear power plant in the construction, operation or decommissioning phase. The group was formally extended in 2003 to include new and future European Union (EU) member states. Currently the following countries are members of WENRA: Belgium, Bulgaria, the Czech Republic, Finland, France, Germany, Hungary, Italy, Lithuania, the Netherlands, Romania, Slovenia, the Slovak Republic, Spain, Sweden, Switzerland and the United Kingdom. Recently Ukraine has joined WENRA, and various other states have been invited to WENRA meetings with the status of “observers.” Representatives from Ukraine, the Russian Federation and Poland participated in the finalisation of this report.

The original objectives of the Association were:

- to provide the EU institutions with an independent capability to examine nuclear safety and regulation in applicant countries,
- to provide the EU with an independent capability to examine nuclear safety and regulation in candidate countries, and
- to evaluate and achieve a common approach to nuclear safety and regulatory issues which arise.

The second objective of WENRA has been fulfilled by the preparation of a report on nuclear safety in candidate countries having at least one nuclear power plant. After May 1st, 2004, when most of these candidate countries became regular EU member states, the new WENRA tasks, based on first and third original Association's objectives, became:

- providing the European Union institutions with an independent capability to examine nuclear safety and regulation in applicant countries and
- developing common approaches to nuclear safety and regulations and to encourage the harmonization of practices.

To perform these tasks two working groups within the WENRA were established – the Reactor Harmonization Working Group (RHWG) and the Working Group on Waste and Decommissioning (WGWD). The work of WGWD started in 2002.

1.1.2 Objective

The objective of this report is to provide SRLs for radioactive waste treatment and conditioning facilities irrespective of:

- the nature of the material to be processed,
- the location (on the waste producer site/in centralized facility),
- the type of conditioning facility (permanently installed/mobile), and
- the design of the process (single step/multi step).

Although the safety objective is the same in the above cases, the means of achieving it may differ considerably depending on the type and amount of waste to be treated as well as the type of process (e.g. vitrification vs. simple packaging). The requirements should accordingly be implemented using a graded approach proportionate to the hazard of the process and the radioactive waste.

A specific issue considered in this report is the use of mobile equipment in Nuclear Power Plants (NPPs) or other nuclear installations. In WENRA countries there are several approaches to the regulation of such activities. In all cases there are technical and organizational interfaces which have to be taken into account and which have been covered by SRLs in this report.

The SRLs in this report apply mainly to licensees, who are responsible for the safety of their facilities until the termination of their licences. However, some requirements cannot be directly or wholly addressed by the licensee as they concern issues such as the national waste management policy or certain interface issues. It is strongly recommended that this report is not used on a standalone basis, but is considered in conjunction with the other relevant WENRA

documents to ensure that all safety issues relevant to waste processing facility are properly addressed.

According to the WENRA policy statement, after the safety reference levels have been produced, they should be incorporated within the national regulatory system within a period of 3-4 years. This means that, for the processing SRLs, WGWD aims to complete the process around the year 2020.

1.1.3 Scope

This report has been largely modelled on previous reports prepared by the WENRA WGWD, but taking into account the particular issues associated with radioactive waste processing. The SRLs apply to the processing of all types of radioactive waste i.e. solids, liquids, slurries etc. The SRLs also apply to treatment and conditioning of spent fuel where designated for direct disposal. The ultimate purpose of waste processing is the production of a qualified product considered suitable for all further steps of waste management. Consequently the report establishes both facility-oriented and process-oriented SRLs. Waste processing is not only performed using permanently installed systems, but also using mobile equipment installed solely for the short period of time needed for the processing campaign. SRLs have therefore been developed to address the additional safety issues associated with mobile equipment.

Materials containing radionuclides of natural origin (NORM - mining and mineral processing waste as referred to in IAEA SSR-5) are not within the scope of this report. Various ways of managing such waste are implemented in different countries, depending on the characteristics and level of activity of the waste. While some of this waste may be processed in facilities covered by this report, any specific aspects relating to NORM-waste such as large volumes, physical state, etc. have not been considered when drafting the processing SRLs.

The processing SRLs address relevant nuclear and waste safety requirements, but do not take into account other regulatory requirements such as Environmental Impact Assessment regulation (required by EU directives), discharge authorization, , management of non-radioactive waste, occupational health and safety, physical protection including safeguards, and funding issues. These other regulatory requirements should be treated in accordance with the applicable national regulatory systems.

With respect to chemical toxicity of the waste, the WGWD recognizes that protection from the non-radioactive hazardous content of the waste is an important issue, especially during waste processing. Some SRLs in this report address the chemical properties of materials and the applied processing techniques. The WGWD members stress the need for this issue to be duly handled by the licensee, so as to comply with any additionally applicable regulatory requirements.

1.1.4 Structure

The report consists of two main parts. Following this introduction, part 2 of the report presents the specific waste processing reference levels and the corresponding appendices. The results of regulators self-assessment and benchmarking exercises will be documented, when available, in part 3 and published in a later version of this report.

1.2

Methodology

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The working methodology of WGWD has gone through several steps and changes since 2002, when the working group was established. A list of topics to be covered by WGWD was defined taking into account the common field of responsibility of WENRA members. Generally for the development of waste processing SRLs the following IAEA documents were considered:

- *Fundamental Safety Principles, IAEA Safety Fundamentals SF-1, Vienna (2006).*
- *Governmental, Legal and Regulatory Framework for Safety, IAEA General Safety Requirements, GSR Part 1, Vienna (2010).*
- *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA General Safety Requirements, GSR Part 3, Vienna (2011).*
- *Safety Assessment for Facilities and Activities, IAEA General Safety Requirements, GSR Part 4, Vienna (2009).*
- *Predisposal Management of Radioactive Waste, IAEA General Safety Requirements, GSR Part 5, Vienna (2009).*
- *Preparedness and Response for a Nuclear or Radiological Emergency, IAEA General Safety Requirements, GS-R-2, Vienna (2002).*
- *Management Systems for Facilities and Activities, Safety Requirements, IAEA General Safety Requirements, GS-R-3, Vienna (2006).¹*
- *Safety of Nuclear Fuel Cycle Facilities, IAEA Safety Requirements, NS-R-5 (Rev. 1), Vienna (2014).*
- *The Safety Case and Safety Assessment for the Predisposal Management of Radioactive Waste, IAEA General Safety Guide, GSG-3, Vienna (2013).*
- *The Management System for the Processing, Handling and Storage of Radioactive Waste, IAEA Safety Guide, GS-G-3.3, Vienna (2008).*
- *Predisposal Management of Low and Intermediate Level Radioactive Waste, IAEA Safety Guide, WS-G-2.5, Vienna (2003).*
- *Predisposal Management of High Level Radioactive Waste, IAEA Safety Guide, WS-G-2.6, Vienna (2003).*
- *Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, IAEA Safety Guide, WS-G-2.7, Vienna (2005).*

¹ IAEA GS-R-3 is currently being revised

- *Storage of Radioactive Waste, IAEA Safety Guide, WS-G-6.1, Vienna (2006).*
- *Storage of Spent Nuclear Fuel, IAEA Specific Safety Guide, SSG-15, Vienna (2012).*
- *Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, IAEA Specific Safety Guide, SSG-41, Vienna (2016).*

Other international/European standards and recommendations relevant to processing of radioactive waste:

- *Joint convention on the safety of spent fuel management and on the safety of radioactive waste management. INFCIRC/546. 24 December 1997.*
- *Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste*
- *Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation*
- *WENRA – Waste and spent fuel storage safety reference levels report, version 2.2*
- *WENRA – Decommissioning safety reference levels report, version 2.2*
- *WENRA – Disposal facilities safety reference levels report, version 1.0*

Requirements were selected and –if necessary- reworded in order to clearly address licensees of waste processing plants, licensees of nuclear installations when using mobile equipment for treatment and conditioning as well as their contractors and owners of radioactive waste with the responsibility of managing their waste. The thematic selection of requirements shall resemble a consistent set of SRLs describing the safety areas

- safety management,
- process and product requirements,
- design,
- operation, and
- safety verification.

Part 2

Radioactive Waste Treatment and Conditioning Safety Reference Levels

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These reference levels apply to the treatment and conditioning of radioactive waste in processing facilities, either as part of other nuclear installations or as stand-alone facilities. They also apply to temporarily installed, mobile treatment and conditioning plant. The reference levels are relevant to a wide range of facilities and thus have to be applied in a proportionate manner, taking account of the magnitude of the hazard associated with the waste. Such a graded approach should also be applied within a facility,

Treatment and conditioning processes frequently involve physical and/or chemical changes such as heat treatment (e.g. incineration), supercompaction and chemical processing. The associated hazards have been considered in the development of the SRLs.

Depending on the individual national waste management systems, the preparation of final waste packages for disposal may be a multistep process with one or more interim phases of storage. WENRA assumes the general principle of a “cradle to grave” responsibility of the waste owner for proper planning of each step in order to arrive at a finally conditioned waste package meeting the waste acceptance criteria (WAC) of a disposal facility. For further discussion of the responsibilities of the various parties see the umbrella document (in preparation).

The selection of an appropriate treatment and conditioning process is complex as the desired properties of the product are influenced by various downstream requirements (for example, interim storage, final disposal, transport) which are not always consistent. The SRLs therefore address the selection of the waste treatment and conditioning process in a specific safety area.

Incoming waste accepted for processing must be consistent the requirements of the facility safety case and the required waste product. SRLs have therefore been developed addressing the specifications for the waste feed, waste product and the process.

2.1

Safety area: Safety management

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2.1.1 Safety issue: Responsibility

P-01:

There shall be clear and unequivocal ownership of radioactive waste, including when accepting foreign waste for processing.

Related IAEA safety standards:

It is possible that the predisposal management of radioactive waste will involve the transfer of radioactive waste from one operator to another, or that radioactive waste may even be processed in another State. In such situations, continuity of responsibility for safety is necessary throughout. (GSR Part 5, para 3.3)

The predisposal management of LILW may involve the transfer of radioactive waste from one operator to another or the processing of LILW in another State. The established legal framework should include provisions to ensure that there is a clear allocation of responsibility for safety during the entire predisposal management process for LILW, including any transfer between operators. [...] (WS-G-2.5, para 3.2)

The predisposal management of HLW may involve the transfer of radioactive waste from one operator to another or the processing of HLW in another State. The established legal framework should include provisions to ensure that there is a clear allocation of responsibility for safety during the entire predisposal management process for HLW, including any transfer between operators. [...] (WS-G-2.6, para 3.2)

P-02:

The waste owner shall provide information about changes of ownership of radioactive waste to the regulatory body prior to the implementation of the changes.

Related IAEA safety standard:

Information about changes of ownership of waste or about changes in the relationship between owner and licensee has to be provided to the regulatory body. (GSR Part 5, para 3.18)

P-03:

The waste owner shall be responsible for the overall strategy for the management of its radioactive waste, taking into account interdependencies between all stages of treatment and conditioning. It shall be consistent with the overall national radioactive waste management strategy.

If no disposal option has been selected the waste owner shall take into account assumptions about the likely disposal option.

Related IAEA safety standards:

The operator² is responsible for establishing and implementing the overall strategy for the management of the waste that is generated and for providing the required financial securities, taking into account interdependences among all steps in waste management, the available options and the national radioactive waste management policy. (GSR Part 5, para 3.17)

Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option, shall be appropriately taken into account.

(GSR Part 5, Requirement 6)

P-04:

The waste owner shall continuously improve the overall strategy for the management of its radioactive waste by using experience feedback and advances in science and technology.

Related IAEA safety standards: (see P-03)

P-05:

The waste owner shall ensure that a system is established and maintained for keeping up-to-date records. For the purposes of all subsequent waste management steps, this system shall include provisions to adequately identify and describe the radioactive waste at whatever stage it has reached.

Related IAEA safety standard:

Depending on the complexity of the operations and the magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means, including: [...]

- *Maintenance of records and reporting as required by the regulatory body, including those records and reports necessary to guarantee the accountability for and traceability of radioactive waste throughout the different processes of radioactive waste management; [...]* (GRS Part 5, para 3.11)

² The term operator is used within GSR Part 5 to subsume generators of radioactive waste as well as operators of predisposal waste management facilities (see GSR Part 5, footnote 2, page 7)

Records generated at all stages of the predisposal management of waste may be important for demonstrating the compliance of the waste package with the specifications. Such records should ensure the traceability of the characteristics of the waste from its collection through to its processing and storage. A system for documentation that includes the development of such records should be established. (WS-G- 2.5, para 8.7, & WS-G- 2.6, para 8.9)

P-06:

The waste owner and the licensee, if they are different organisations, shall jointly agree and document the respective responsibilities of each organisation.

Related IAEA safety standard:

It is possible that the predisposal management of radioactive waste will involve the transfer of radioactive waste from one operator to another, or that radioactive waste may even be processed in another State. In such situations, continuity of responsibility for safety is necessary throughout.

(GSR Part 5, para 3.3)

P-07:

The licensee shall be responsible for the safety of the facility.

Related IAEA safety standard:

The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks. (SF-1, Principle 1)

The licensee is responsible for: [...]

– Establishing procedures and arrangements to maintain safety under all conditions; [...]

(SF-1, para 3.6)

P-08:

The licensee shall establish and implement its safety policy taking due account of national and international standards and ensure that matters related to safety are given the highest priority.

Related IAEA safety standard:

The operating organization:

(a) Shall establish and implement safety, health and environmental policies in accordance with national and international standards and shall ensure that these matters are given the highest priority; [...]

(NS-R-5 (Rev. 1), para 4.2)

P-09:

The licensee shall continuously improve safety by using experience feedback and advances in science and technology.

Related IAEA safety standard:

[...] Processes must be put in place for the feedback and analysis of operating experience, including initiating events, accident precursors, near misses, accidents and unauthorized acts, so that lessons may be learned, shared and acted upon. (SF-1, para 3.17)

Potential non-conformances that could detract from the organization's performance shall be identified. This shall be done: by using feedback from other organizations, both internal and external; through the use of technical advances and research; through the sharing of knowledge and experience; and through the use of techniques that identify best practices. (GS-R-3, para 6.16)

P-10:

The licensee shall ensure that all activities, including those carried out by contractors, are performed and controlled according to the licensee's management system.

Related IAEA safety standard:

Management systems shall be applied for all steps and elements of the predisposal management of radioactive waste. (GRS Part 5, Requirement 7)

Where appropriate, the operator may delegate work associated with the aforementioned responsibilities to other organizations, but the operator has to retain overall responsibility and control. (GSR Part 5, para 3.14)

[...] The operator is responsible for the safety of all activities in the predisposal management of waste, even if the work is contracted to a third party. [...] (WS-G-2.6, para 3.12 & WS-G-2.5, para 3.12)

P-11:

The licensee shall ensure that the resources in terms of staffing, skills, experience and knowledge for all licensed activities will be available at the time they are needed.

Related IAEA safety standard:

The operating organization shall maintain the capability in terms of staffing, skills, experience and knowledge to undertake competently all activities throughout the lifetime of the facility, from its siting to decommissioning. Where the resources and skills necessary to fulfil any part of these undertakings are provided by an external organization, the operating organization shall nevertheless retain within its organization the capability to assess the adequacy of the external organization's capabilities for ensuring safety. (NS-R-5, para 4.9)

Depending on the complexity of the operations and the magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means, including: [...]

- *Ensuring that staff are trained, qualified and competent, and, where applicable, licensed by the regulatory body;*
- *Establishment and implementation of a management system; [...]*

(GSR Part 5, para 3.11)

P-12:

The licensee shall carry out safety assessments and shall develop safety cases in compliance with legal and regulatory requirements.

Related IAEA safety standard:

Operators shall be responsible for the safety of predisposal radioactive waste management facilities or activities. The operator shall carry out safety assessments and shall develop a safety case, and shall ensure that the necessary activities for siting, design, construction, commissioning, operation, shutdown and decommissioning are carried out in compliance with legal and regulatory requirements.

(GSR Part 5, Requirement 4)

P-13:

The licensee shall establish and maintain emergency preparedness and response plans proportionate to the hazards associated with the facility and activities, and it shall report accidents and incidents significant to safety in a timely manner to the regulatory body and other interested parties, as appropriate.

Related IAEA safety standard:

The operator is required to establish and maintain emergency preparedness and response plans commensurate with the hazards associated with the radioactive waste facilities and activities, and to report incidents significant to safety in a timely manner to the regulatory body and other interested parties, as appropriate (GSR Part 5, para 3.13)

2.1.2 Safety issue: Organisational structure

P-14:

The licensee shall establish an organizational structure to enable its safety policy to be delivered, with a clear definition of responsibilities and accountabilities, lines of authority and communication, including when contractors are involved in the processing activities.

Related IAEA safety standard:

The operating organization shall establish an organizational structure to enable these policies to be carried out with a clear definition of responsibilities and accountabilities, lines of authority and communication. (NS-R-5 (Rev. 1), para 4.2)

The interdependences among the steps in the predisposal management of LILW should be considered for achieving continuity in operations. The following aspects in particular should be considered:

- (a) The identification of interfaces and the definition of the responsibilities of the various organizations involved at these interfaces; (...) (WS-G-2.5, para 4.2)*

The interdependences among the steps in the predisposal management of HLW should be considered so as to facilitate continuity in operations. The following aspects in particular should be considered:

- (a) The identification of interfaces and the definition of the responsibilities of the various organizations involved at these interfaces. (...) (WS-G-2.6, para 4.2)*

P-15:

The licensee shall establish and maintain the capability in terms of the staffing, skills, experience and knowledge required to undertake all processing activities.

Related IAEA safety standard:

The operating organization shall maintain the capability in terms of staffing, skills, experience and knowledge to undertake competently all activities during the lifetime of the facility from siting to de-commissioning. (NS-R-5 (Rev. 1), para 4.9)

P-16:

The licensee shall specify the necessary qualifications, experience and skills for all staff involved in processing activities and waste characterization and shall ensure that training programmes are established for developing and maintaining the professional skills of the staff.

Related IAEA safety standard:

The operating organization shall specify the necessary qualifications and experience for all staff involved in activities that may affect safety. It shall also specify appropriate requirements on training and its assessment and approval. (NS-R-5 (Rev. 1), para 4.10)

[...]. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives. (GS-R-3, para 4.4)

Minimum qualifications for personnel shall be specified, and these minimum qualifications shall be commensurate with the assigned functional responsibility and authority. (NS-R-5 (Rev. 1), para 9.8)

P-17:

Where any activity related to safety is carried out by a contractor, the licensee shall retain within its organization the capability to assess the adequacy of the contractor's resources and skills for ensuring safety and the quality of the deliverables.

Related IAEA safety standard:

[...] Where the resources and skills necessary to fulfil any part of these undertakings are provided by an external organization, the operating organization shall nevertheless retain within its organization the capability to assess the adequacy of the external organization's capabilities for ensuring safety.

(NS-R-5 (Rev.1), para 4.9)

2.1.3 Safety issue: Management system

P-18:

The licensee shall establish a management system applicable to all activities performed in the facility. The management system shall be subject to continuous improvement.

Related IAEA safety standard:

Management systems shall be applied for all steps and elements of the predisposal management of radioactive waste [...] (GSR Part 5, Requirement 7)

A management system shall be established, implemented, assessed and continually improved.

(GS-R-3, para 2.1)

P-19:

The licensee's management system shall achieve and enhance safety by:

- bringing together in a coherent manner all the requirements for managing the organization,
- describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied,
- ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.

Related IAEA safety standard:

[...] The main aim of the management system shall be to achieve and enhance safety by:

- *Bringing together in a coherent manner all the requirements for managing the organization;*
- *Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;*

- *Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety. (GS-R-3, para 2.1; also cited in GS-G-3.3, para 2.1)*

P-20:

The licensee shall identify the processes in the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization, and their development shall be planned, implemented, assessed and continually improved. The work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness.

Related IAEA safety standard:

The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved. (GS-R-3, para 5.1)

The work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results shall be compared with expected values.

(GS-R-3, para 5.9)

P-21:

The licensee shall document in its management system the following as a minimum:

- its safety policy;
- a description of its management system;
- a description of its organizational structure;
- a description of its quality assurance programme;
- a description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;
- a description of the licensee's interactions with contractors, including the control of activities carried out by contractors;
- a description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved; and,
- a description of the provisions to record and review knowledge, information and data about all aspects related to safety of the facility and to preserve the records.

Related IAEA safety standard:

The documentation of the management system shall include the following:

- *The policy statements of the licensee;*
- *A description of the management system;*
- *A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;*
- *A description of the interactions with relevant external organizations;*
- *A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved. (GS-R-3, para 2.8)*

The documentation of the management system shall reflect:

- *The characteristics of the organization and its activities;*
- *The complexities of processes and their interactions. (GS-R-3, para 2.10)*

2.1.4 Safety issue: Documentation and record management

P-22:

The licensee shall develop and maintain a record management system for detailing the characteristics and location of every radioactive waste in the facility, containing at least the following information:

- The mass and/or volume,
- The radiological characteristics,
- The chemical and physical form,
- The source or origin,
- Any chemical, pathogenic or other hazards associated with the waste and the concentrations of hazardous material; and,
- Any special handling necessary owing to criticality concerns, the need for the removal of decay heat or significantly elevated radiation fields.

Related IAEA safety standard:

A waste characterization record should contain the following information pertaining to the waste:

- (a) The source or origin;*
- (b) The physical and chemical form;*
- (c) The amount (volume and/or mass);*
- (d) The radiological characteristics (the activity concentration, the total activity, the radionuclides present and their relative proportions);*
- (e) The classification in accordance with the national waste classification system;*
- (f) Any chemical, pathogenic or other hazards associated with the waste and the concentrations of hazardous material;*
- (g) Any special handling necessary owing to criticality concerns, the need for the removal of decay heat or significantly elevated radiation fields.*

(WS-G- 2.5, para 6.3, & WS-G- 2.6, para 6.3)

The operating organization should develop and maintain a records system on spent fuel data and on the storage system, which includes the radioactive inventory, location and characteristics of the spent fuel, information on ownership, origin and information about its characterization. [...]

(SSG-15, para 3.27)

P-23:

The licensee's record management system shall enable traceability from the receipt of the incoming waste to the dispatch of the processed waste.

Related IAEA safety standard:

Depending on the complexity of the operations and the magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means, including: [...]

- *Maintenance of records and reporting as required by the regulatory body, including those records and reports necessary to guarantee the accountability for and traceability of radioactive waste throughout the different processes of radioactive waste management; [...]* (GSR Part 5, para 3.11)

Records generated at all stages of the predisposal management of waste may be important for demonstrating the compliance of the waste package with the specifications. Such records should ensure the traceability of the characteristics of the waste from its collection through to its processing and storage. A system for documentation that includes the development of such records should be established. (WS-G- 2.5, para 8.7, & WS-G- 2.6, para 8.9)

P-24:

The licensee's record management system shall include up-to-date information on the radioactive waste inventory within the facility as required by the safety case.

Related IAEA safety standard:

It should be the responsibility of the operator: [...]

(h) To establish and keep records of information on the generation, processing, storage and disposal of radioactive waste, including the maintenance of an up to date inventory of stored radioactive waste; [...] (WS-G-2.7, para 3.18)

A tracking system for waste packages should be developed and implemented. The system should provide for the identification of waste packages and their locations and an inventory of waste stored. [...] (WS-G-6.1, para 4.11)

P-25:

The licensee shall establish provisions to allow for unequivocal identification of each outgoing product.

Related IAEA safety standard:

Products shall be identified to ensure their proper use. Where traceability is a requirement, the organization shall control and record the unique identification of the product. (GS-R-3, para 5.19)

2.1.5 Safety issue: Product quality

P-26:

The licensee's quality assurance programme (see P-21) shall include

- (a) specifications of the properties for the incoming waste for the purposes of operational safety and product quality;
- (b) determination of any process variables relevant to product quality and establishment of the limits or tolerances for those process variables;
- (c) specifications of procured items or services relevant to product quality; and
- (d) determination of adequate control methods, including the nature and frequency of required sampling or testing.

Related IAEA safety standard:

Waste packages and unpackaged waste that are accepted for processing, storage and/or disposal shall conform to criteria that are consistent with the safety case. (GSR Part 5, Requirement 12)

The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved. (GS-R-3, para 5.1)

The development of each process shall ensure that the following are achieved:

- *Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic requirements, are specified and addressed. (...)*
- *Process inputs are identified.*
- *The process flow is described.*
- *Process outputs (products) are identified.*
- *Process measurement criteria are established. (GS-R-3, para 5.4)*

Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the organization before the product is used.

(GS-R-3, para 5.24)

For each process, any activities for inspection, testing, verification and validation, their acceptance criteria and the responsibilities for carrying out these activities shall be specified. For each process, it shall be specified if and when these activities are to be performed by designated individuals or groups other than those who originally performed the work. (GS-R-3, para 5.7)

Work processes affecting the safety, health, environmental, security, quality and economic requirements of waste management activities and the quality of the outputs (e.g. discharged or cleared materials, packaged waste) should be controlled so that:

(a) The applicable prerequisites, including environmental conditions, physical parameters, equipment characteristics and personnel competences, are satisfied;

(b) All process variables are kept within specified acceptance criteria. (GS-G-3.3, para 5.11)

2.2

Safety area: Process and product requirements

—

2.2.1 Safety Issue: General principles

P-27:

The licensee shall process radioactive waste in a form suitable for the subsequent steps of waste management.

Related IAEA safety standard:

[...] The processing of radioactive waste shall be based on appropriate consideration of the characteristics of the waste and of the demands imposed by the different steps in its management (pretreatment, treatment, conditioning, transport, storage and disposal). [...]

(GSR Part 5, Requirement 10)

The main purpose of processing radioactive waste is to enhance safety by producing a waste form, packaged or unpackaged, that fulfils the acceptance criteria for safe processing, transport, storage and disposal of the waste.[...] (GSR Part 5, para 4.13)

P-28:

In addition to radioactivity, the licensee shall take into account all properties of the radioactive waste that may affect safety during processing.

Related IAEA safety standard:

Radioactive waste has to be characterized in terms of its physical, mechanical, chemical, radiological and biological properties. (GSR Part 5, para 4.10)

Depending on the complexity of the operations and the magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means, including: (...)

- *Consideration of non-radiological hazards and conventional health and safety issues.*

(GSR Part 5, para 3.11)

2.2.2 Safety Issue: Selection of process

P-29:

The licensee shall consider all relevant factors when selecting the processing options, including:

- nuclear and radiation safety
- discharges
- minimisation of secondary waste
- quality assurance
- product specifications

Related IAEA safety standard:

Various methods are applied for processing radioactive waste of different types. Consideration has to be given to identifying suitable options and to assessing the appropriateness of their application. Decisions have to be taken within the overall approach to the predisposal management of radioactive waste on the extent to which the waste has to be processed, with account taken of the quantities, activity and physical and/or chemical nature of the radioactive waste to be treated, the technologies available, the storage capacity and the availability of a disposal facility. (GSR Part 5, para 4.15)

The design of the facility, the arrangements for operational management and the systems and processes that are used have to be considered and justified in the safety case. This has to involve the identification of waste arisings and the establishment of an optimal programme of waste management to minimize the amount of waste generated and to determine the design basis and operational basis for the treatment of effluents, the control of discharges and clearance procedures. The primary aim of the safety case is to ensure that the safety objectives and criteria set by the regulatory body are met.

(GSR Part 5, para 5.5)

The operator should specify and evaluate a range of options for managing LILW and should justify the preferred selection. Factors that should be taken into account include:

- (a) The types, physical properties, chemical composition, volumes and radionuclide content of existing radioactive waste inventories and forecasts for the future generation of radioactive waste;*
- (b) The authorized acceptance criteria for radioactive waste for all management steps, including storage and disposal;*
- (c) The availability of appropriate facilities and disposal options;*
- (d) The availability of appropriate processing technologies;*
- (e) The regulatory requirements for authorized use, authorized discharges and removal of regulatory control. (WS-G- 2.5, para 4.6)*

[...] Waste minimization relates to both volume and activity and to both the waste generated by an initial undertaking and the secondary waste resulting from the predisposal management of radioactive waste. The chemical characteristics of the waste should also be controlled at the source to facilitate the subsequent processing of the waste. (WS-G-2.5, para 4.7)

2.2.3 Safety Issue: Properties of processed waste

P-30:

The licensee shall describe the required product in a specification defining the following properties:

- radiological,
- physical,
- chemical,
- biological
- geometrical
- traceability/labelling.

Related IAEA safety standard:

Radioactive waste has to be characterized in terms of its physical, mechanical, chemical, radiological and biological properties. (GSR Part 5, para 4.10)

The characterization serves to provide information relevant to process control and assurance that the waste or waste package will meet the acceptance criteria for processing, storage, transport and disposal of the waste. The relevant characteristics of the waste have to be recorded to facilitate its further management. (GSR Part 5, para 4.11)

Products shall be identified to ensure their proper use. Where traceability is a requirement, the organization shall control and record the unique identification of the product. (GS-R-3, para 5.19)

P-31:

The organisation responsible for selecting the type of waste packaging shall ensure its compatibility with the properties of the waste form and with the subsequent steps of waste management.

Related IAEA safety standard:

[...]The processing of radioactive waste shall be based on appropriate consideration of the characteristics of the waste and of the demands imposed by the different steps in its management (pretreatment, treatment, conditioning, transport, storage and disposal). Waste packages shall be designed and produced so that the radioactive material is appropriately contained both during normal operation and in accident conditions that could occur in the handling, storage, transport and disposal of waste. (GSR Part 5, Requirement 10)

Radioactive waste has to be processed in such a way that the resulting waste form can be safely stored and retrieved from the storage facility up until its ultimate disposal. (GSR Part 5, para 4.16)

2.3

Safety area: Design

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2.3.1 Safety issue: Facility design requirements

P-32:

The licensee shall design the facility to fulfil the fundamental applicable safety functions including:

- control of sub-criticality,
- removal of heat,
- radiation shielding; and,
- confinement of radioactive material.

These will apply during normal operation, anticipated operational occurrences and design basis accident conditions.

Related IAEA safety standard:

[...] As far as practicable, criticality hazards shall be controlled by means of design.

(NS-R-5 (Rev. 1), para 6.43)

[...] Heat generation shall be taken into account, as appropriate, in the facility design.

(NS-R-5 (Rev. 1), para 6.52)

Protection against radiation exposure shall be achieved by means of engineered provisions such as adequate shielding and the use of remote handling equipment. (NS-R-5 (Rev. 1), para 6.40)

The main design features for the control of contamination are confinement and leak detection. Confinement is achieved by means of physical barriers (static containment) and/or dynamic containment (e.g. by ventilation). The nature and number of the barriers and their performance, as well as the performance of air purification systems, shall be commensurate with the degree of the potential hazards, with special attention paid to the potential dispersion of alpha emitters.

(NS-R-5 (Rev. 1), para 6.38)

In the design of a facility for the predisposal management of LILW, due consideration should be given to the need for:

(h) Protection against radiation exposure (by shielding and containment);

[...]

(l) The prevention of criticality; [...] (WS-G-2.5, para 5.7)

[...] the design of a predisposal management facility for HLW should include features (engineering controls) to maintain containment, remove decay heat, control gaseous and liquid effluents, and prevent criticality, especially when concentrating HLW to reduce its total volume. The use of administrative controls as part of the defence in depth approach should be considered, although engineered controls are preferable. (WS-G-2.6, para 5.2)

P-33:

The licensee shall design the facility in such a way that the quality of the product can be assured.

Related IAEA safety standard:

In the design and safety justification for the facility, not only the facility itself but also the interfaces with other facilities and installations that may affect its safety shall be considered.

(NS-R-5 (Rev. 1), para 6.3)

To ensure the safety of predisposal radioactive waste management facilities and the fulfilment of waste acceptance criteria, management systems are to be applied to the siting, design, construction, operation, maintenance, shutdown and decommissioning of such facilities and to all aspects of processing, handling and storage of waste. [...] (GSR Part 5, para 3.24)

P-34:

The licensee shall in its design of the facility take into account the expected operational lifetime of the facility to ensure that the safety conditions and the operational limits and conditions identified in the safety case will be met.

Related IAEA safety standard:

Predisposal radioactive waste management facilities shall be located and designed so as to ensure safety for the expected operating lifetime under both normal and possible accident conditions, and for their decommissioning. (GSR Part 5, Requirement 17)

P-35:

The licensee shall design the facility to ensure that safety is achieved through the use of safety features with preference of passive safety features as far as practicable. The licensee shall give preference to prevention over mitigation.

Related IAEA safety standard:

The following hierarchy of design measures shall be used to the extent practicable in protecting against potential hazards:

- (1) Selection of the process (to eliminate the hazard);*
- (2) Passive design features;*

- (3) Active design features;
- (4) Administrative controls. (NS-R-5 (Rev. 1), para 6.6)

A facility for the predisposal management of LILW should be designed so that as far as possible incidents will be avoided and accidents will be prevented, and if they do occur the consequences will be mitigated. (WS-G-2.5, para 2.6)

Owing to the high radionuclide concentrations and high radiation levels associated with HLW, its predisposal management has the potential to give rise to significant exposure to radiation of workers and members of the public. Particular emphasis should therefore be placed on the prevention, detection and mitigation of incidents and accidents in the design, operation and decommissioning of facilities for the management of HLW. (WS-G-2.6, para 2.3)

P-36:

The licensee shall base the design of the facility on applicable standards, appropriately proven techniques and the use of appropriate materials to ensure that the safety requirements will be met.

Related IAEA safety standard:

Design criteria for all relevant parameters shall be specified for each operational state of the facility and for each design basis accident or equivalent. Design criteria for SSCs important to safety may be in the form of engineering design rules. Engineering design rules include requirements in relevant codes and standards, and may be set and required explicitly by the regulatory body by requiring the use of applicable standard engineering practices already established in the State or used internationally. [...]

(NS-R-5 (Rev.1), para 6.11)

P-37:

The licensee shall establish a design basis for the facility taking into account normal operation, anticipated operational occurrences and possible accidents derived from a relevant set of Postulated Initiating Events (PIEs).

Related IAEA safety standard:

The operating organization shall identify postulated initiating events that could lead to a release of radiation and/or significant amounts of radioactive material and associated chemical substances. The resulting set of identified postulated initiating events shall be confirmed to be comprehensive and shall be defined in such a way that the events cover credible failures of the SSCs of the facility and human errors that could occur in any of the operating conditions of the facility. The set of postulated initiating events shall include both internally and externally initiated events. [...] (NS-R-5 (Rev. 1) para 6.8)

Design criteria for all relevant parameters shall be specified for each operational state of the facility and for each design basis accident or equivalent. Design criteria for SSCs important to safety may be in the form of engineering design rules. Engineering design rules include requirements in relevant codes and

standards, and may be set and required explicitly by the regulatory body by requiring the use of applicable standard engineering practices already established in the State or used internationally. [...]

(NS-R-5 (Rev.1), para 6.11)

P-38:

The licensee shall make design arrangements for fire safety on the basis of a fire safety analysis and implementation of defence in depth (prevention, detection, control and mitigation of a fire).

Related IAEA safety standard:

The operating organization shall make design provisions for fire safety on the basis of a fire safety analysis and the implementation of the concept of defence in depth (i.e. for prevention, detection, control and mitigation). (NS-R-5 (Rev. 1), para 6.55)

P-39:

The licensee shall identify and classify Structures, Systems and Components (SSCs) in accordance with their importance for both operational safety and product quality, applying a graded approach.

Related IAEA safety standard:

The safety functions and the structures, systems and components (SSCs) important to safety shall be identified in the safety analysis report to the extent appropriate and in accordance with a graded approach. The SSCs important to safety provide means for the prevention of the occurrence of postulated initiating events, the control and limitation of accident sequences, and mitigation of the consequences. (NS-R-5 (Rev. 1), para 2.12)

P-40:

The licensee shall make design provisions for maintenance, testing, and inspection of Structures, Systems and Components (SSCs).

Related IAEA safety standard:

SSCs important to safety shall be designed to facilitate maintenance, inspection and testing for their functional capability over the lifetime of the facility. (NS-R-5 (Rev.1), para 6.18)

The need for operational maintenance, testing, examination and inspection has to be addressed from the conceptual design stage onward. (GSR Part. 5, para 5.14)

2.4

Safety area: Operation

—

2.4.1 Safety issue: General requirements

P-41:

The licensee shall establish, substantiate, document and implement Operational Limits and Conditions (OLCs) for the facility in accordance with the conditions of the licence and the relevant regulatory requirements to maintain its safety and to achieve suitable product quality.

Related IAEA safety standard:

The operator has to ensure an adequate level of protection and safety by various means, including: [...] Derivation of operational limits, conditions and controls, including waste acceptance criteria, to assist with ensuring that the predisposal radioactive waste management facility is operated in accordance with the safety case; [...] (GSR Part 5, para 3.11)

[...] All operations and activities important to safety have to be subject to documented limits, conditions and controls, and have to be carried out by trained, qualified and competent personnel.

(GSR Part 5, 5.19)

P-42:

The licensee shall operate the facility in accordance with documented procedures.

Related IAEA safety standard:

Predisposal radioactive waste management facilities shall be operated in accordance with national regulations and with the conditions imposed by the regulatory body. Operations shall be based on documented procedures. [...] (GSR Part 5, Requirement 19)

P-43:

The licensee shall process the radioactive waste in such a way that safety is ensured during normal operation, that measures are taken to prevent the occurrence of incidents or accidents, and that provisions are made to mitigate the consequences if accidents occur.

Related IAEA safety standard:

Waste has to be processed in such a way that safety is appropriately ensured during normal operation, that measures are taken to prevent the occurrence of incidents or accidents, and that provisions are made to mitigate the consequences if accidents occur.[...] (GSR Part 5, para 4.14)

P-44:

The licensee shall establish provisions for identifying, assessing and dealing with products that do not meet product specifications.

Related IAEA safety standard:

Provisions have to be established by the operator for identifying, assessing and dealing with waste and/or waste packages that do not meet process specifications and requirements for its and/or their safe handling, transport, storage and/or disposal. (GSR Part 5, para 4.17)

P-45:

The licensee shall make arrangements for managing any secondary waste created during processing.

Related IAEA safety standard:

Consideration has to be given to the consequences of dealing with any secondary waste (both radioactive and non-radioactive) that is created during processing. (GSR Part 5, para 4.18)

2.4.2 Safety issue: Emergency preparedness

P-46:

Based upon an assessment of reasonably foreseeable events and situations that may require protective measures, the licensee shall provide arrangements for responding effectively to events requiring protective measures at the scene for:

- regaining control of any emergency arising at the site, including events related to combinations of non-nuclear and nuclear hazards;
- preventing or mitigating the consequences; and,
- co-operating, where necessary with external emergency response organizations in preventing adverse health effects in workers and the public.

Related IAEA safety standard:

Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents. (SF-1, Principle 9)

The primary goals of preparedness and response for a nuclear or radiation emergency are:

- *To ensure that arrangements are in place for an effective response at the scene and, as appropriate, at the local, regional, national and international levels, to a nuclear or radiation emergency;*
- *To ensure that, for reasonably foreseeable incidents, radiation risks would be minor;*
- *For any incidents that do occur, to take practical measures to mitigate any consequences for human life and health and the environment. (SF-1, para 3.34)*

Arrangements for the co-ordination of emergency response and protocols for operational interfaces between operators and local, regional and national governments shall be developed, as applicable. These arrangements shall include the organizations responsible for emergency services and for response to conventional emergencies. The arrangements shall be clearly documented and this documentation shall be made available to all relevant parties. (GSR-R-2, para 5.10)

P-47:

The licensee shall:

- prepare an on-site emergency plan as a basis for the preparation and implementation of emergency measures;
- establish the necessary organizational structure for clear allocation of responsibilities, authorities and arrangements for coordinating facility activities and cooperating with emergency response organizations throughout all phases of an emergency; and,
- ensure that trained and qualified personnel, together with the facilities and equipment needed to control an emergency, are available should they be required.

Related IAEA safety standard:

The appropriate responsible authorities shall ensure that:

- emergency plans [are] prepared and approved for any practice or source which could give rise to a need for emergency intervention;*
- [response organizations are] involved in the preparation of emergency plans, as appropriate;*
- the content, features and extent of emergency plans take into account the results of any [threat assessment] and any lessons learned from operating experience and from [emergencies] that have occurred with sources of a similar type [...];*
- emergency plans [are] periodically reviewed and updated.” [...] (GS-R-2, para 5.17)*

(See also P-49)

P-48:

The licensee shall submit to the regulatory body the on-site emergency plan for approval. At regular intervals, the licensee shall carry out emergency exercises, some of which shall include the participation of external emergency response organizations. The plan shall be subject to review and updating in the light of experience gained.

Related IAEA safety standard:

In developing the emergency response arrangements, consideration has to be given to all reasonably foreseeable events. Emergency plans have to be exercised periodically to ensure the preparedness of the organizations having responsibilities in emergency response. (SF-1, para 3.37)

(...) Emergency preparedness and response plans, if developed by the operator, are subject to the approval of the regulatory body. (GSR Part 5, Requirement 19)

2.4.3 Safety issue: Operating experience feedback

P-49:

The licensee shall establish and conduct an Operating Experience Feedback (OEF) programme to systematically collect, screen, analyse and document operating experience relevant to safety and product quality as well as events at the facility. Relevant operational experience and events reported by other facilities shall be considered as appropriate.

Related IAEA safety standard:

The feedback of operating experience from facilities and activities - and, where relevant, from elsewhere - is a key means of enhancing safety. Processes must be put in place for the feedback and analysis of operating experience, including initiating events, accident precursors, near misses, accidents and unauthorized acts, so that lessons may be learned, shared and acted upon. (SF-1, para 1.17)

The safety assessment and the management systems within which it is conducted have to be periodically reviewed at predefined intervals in accordance with regulatory requirements. In addition to such predefined periodic reviews, the safety assessment has to be reviewed and updated: [...]

- *When there are significant developments in knowledge and understanding (such as developments arising from research or operational experience feedback); [...] (GSR Part 5, para. 5.12)*

P-50:

The licensee shall respond to relevant operating experience by implementing, where necessary, appropriate measures to improve operating practices.

Related IAEA safety standard:

The process of safety assessment for facilities and activities is repeated in whole or in part as necessary later in the conduct of operations in order to take into account changed circumstances (such as the application of new standards or scientific and technological developments), the feedback of operating experience, modifications and the effects of ageing. [...] (SF-1, para 1.16)

The feedback of operating experience from facilities and activities - and, where relevant, from elsewhere - is a key means of enhancing safety. Processes must be put in place for the feedback and

analysis of operating experience, including initiating events, accident precursors, near misses, accidents and unauthorized acts, so that lessons may be learned, shared and acted upon. (SF-1, para 1.17)

2.4.4 Safety issue: Facility modification

P-51:

The licensee shall establish and implement arrangements to control modifications, e. g. of design, equipment, waste processing conditions, waste characteristics, control or management. Proposed modifications shall be subject to planning, assessment, review and authorization arrangements proportionate to the importance to safety of the modification. These arrangements shall ensure that the modifications will not have an unacceptable effect on the safety of the facility or associated facilities, or the quality of the product.

Related IAEA safety standard:

The safety assessment and the management systems within which it is conducted have to be periodically reviewed at predefined intervals in accordance with regulatory requirements. In addition to such predefined periodic reviews, the safety assessment has to be reviewed and updated:

- *When there is any significant change that may affect the safety of the facility or activity;*
- *When there are significant developments in knowledge and understanding (such as developments arising from research or operational experience feedback);*
- *When there is an emerging safety issue owing to a regulatory concern or an incident;*
- *When there have been significant improvements in assessment techniques such as computer codes or input data used in the safety analysis. (GSR Part 5, para 5.12)*

The operating organization shall establish a process whereby its proposals for changes in design, equipment, feed material characteristics, control or management are subject to a degree of assessment and scrutiny appropriate to the safety significance of the change, so that the direct and wider consequences of the modification are adequately assessed. The process shall include a review of possible consequences to ensure that a foreseen modification or change in one facility will not adversely affect the operability or safety of associated or adjacent facilities (NS-R-5 (Rev.1), para 9.35)

P-52:

Before implementing a modification according to P-51, the licensee shall update all affected documents and train the staff in the revised procedures.

Related IAEA safety standard:

The safety assessment and the management systems within which it is conducted have to be periodically reviewed at predefined intervals in accordance with regulatory requirements. In addition to such predefined periodic reviews, the safety assessment has to be reviewed and updated:

- *When there is any significant change that may affect the safety of the facility or activity; [...]*
(GSR Part 5, para 5.12)

The operator has to ensure an adequate level of protection and safety by various means, including: [...]

- *Ensuring that staff are trained, qualified and competent, and, where applicable, licensed by the regulatory body; (GSR Part 5, para 3.11)*

2.4.5 Safety issue: Maintenance, periodic testing and inspection

P-53:

The licensee shall conduct a maintenance, periodic testing and inspection programme according to written procedures in order to ensure that SSCs are able to function in accordance with the design intents and safety requirements.

Related IAEA safety standard:

The licensing documentation shall also define the required intervals for periodic testing and inspection of SSCs important to safety. (NS-R-5 (Rev.1), para 2.14)

Maintenance, calibration, periodic testing and inspection shall be performed to ensure that SSCs important to safety are able to function in accordance with the design intent and with safety requirements. [...] (NS-R-5 (Rev.1), para 9.28)

P-54:

The licensee shall ensure that the programme for maintenance, periodic testing and inspection of SSCs is in accordance with the facility safety case.

Related IAEA safety standard:

The frequency for maintenance, calibration, periodic testing and inspection of SSCs shall be in accordance with the facility licensing documentation. (NS-R-5 (Rev.1), para 9.30)

P-55:

The licensee shall ensure that the results of maintenance, periodic testing and inspection are recorded and assessed to identify any effect on safety and product quality and take any necessary measures for improvement.

Related IAEA safety standard:

The results of maintenance, testing and inspection shall be recorded and assessed.

(NS-R-5 (Rev.1), para 9.32)

P-56:

The licensee shall ensure that the maintenance, periodic testing and inspection programmes are reviewed at regular intervals to incorporate the lessons learned from experience.

Related IAEA safety standard:

The maintenance, calibration, periodic testing and inspection programmes shall be reviewed at regular intervals to incorporate the lessons learned from experience. (NS-R-5 (Rev.1), para 9.33)

2.4.6 Safety issue: Acceptance of incoming waste

P-57:

The licensee shall implement procedures for the receipt of radioactive waste to ensure that the characteristics of the waste accepted for processing comply with the input specification.

Related IAEA safety standard:

Waste packages and unpackaged waste that are accepted for processing, storage and/or disposal shall conform to criteria that are consistent with the safety case. (GSR Part 5, Requirement 12)

P-58:

The licensee shall provide contingency procedures to deal with incoming waste not compliant with the input specification.

Related IAEA safety standard:

Provisions shall be made for identifying, assessing and dealing with waste or waste packages that do not meet process specifications or disposal criteria. (SF-1, para 4.5)

The operators' procedures for the reception of waste have to contain provisions for safely managing waste that fails to meet the acceptance criteria; for example, by taking remedial actions or by returning the waste. (GSR Part 5, para 4.26)

2.4.7 Safety issue: Operational records and verification of product properties

P-59:

The licensee shall make and keep records for incoming waste accepted for processing according to the record management system specified in P-22.

Related IAEA safety standard:

At various stages in the process of predisposal management of radioactive waste, the radioactive waste shall be characterized in terms of its physical, chemical, radiological and biological properties. Such characterization shall serve to provide information relevant to process control and assurance that the waste or waste package will meet the acceptance criteria for storage, transport and disposal. Provisions shall be made for identifying, assessing and dealing with waste or waste packages that do not meet process specifications or disposal criteria. Appropriate collection or segregation may expedite the achievements of such goals. (SF-1, para 4.5)

A waste characterization record should contain the following information pertaining to the waste:

- (a) The source or origin;*
- (b) The physical and chemical form;*
- (c) The amount (volume and/or mass);*
- (d) The radiological characteristics (the activity concentration, the total activity, the radionuclides present and their relative proportions);*
- (e) The classification in accordance with the national waste classification system;*
- (f) Any chemical, pathogenic or other hazards associated with the waste and the concentrations of hazardous material;*
- (g) Any special handling necessary owing to criticality concerns, the need for the removal of decay heat or significantly elevated radiation fields. (WS-G-2.5, para 6.3)*

P-60:

The licensee shall make and keep records of operational data that may prove relevant to either operational safety or product quality.

Related IAEA safety standard:

The operating organization shall make arrangements for generating and controlling records and reports that have safety significance for the operation and decommissioning stages, including: [...]

- (d) Procedures and operating instructions;*
- (e) History of and data on modifications;*
- (f) Operational data for the facility;*
- (g) Data from maintenance, testing, surveillance and inspection;*
- (h) Reports on events and incidents; [...]*
- (n) Records of the main work activities performed in each location of the facility.*

(NS-R-5 (Rev.1), para 9.18)

Traceability refers to the possibility of following the information that is provided in the documentation and that has been used in developing the safety case. For the purposes of both justification and traceability, a well documented record is necessary of the decisions and assumptions that were made in the development and operation of the facility, and of the models and data used in the safety assessment to obtain the set of results. [...] (GSR Part 5, para 5.9)

Depending on the complexity of the operations and the magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means, including: [...]

—Maintenance of records and reporting as required by the regulatory body, including those records and reports necessary to guarantee the accountability for and traceability of radioactive waste throughout the different processes of radioactive waste management; [...] (GSR Part 5, para 3.11)

P-61:

The licensee shall implement procedures to ensure that the product complies with the specifications and make and keep the relevant records.

Related IAEA safety standard:

At various stages in the process of predisposal management of radioactive waste, the radioactive waste shall be characterized in terms of its physical, chemical, radiological and biological properties. Such characterization shall serve to provide information relevant to process control and assurance that the waste or waste package will meet the acceptance criteria for storage, transport and disposal. Provisions shall be made for identifying, assessing and dealing with waste or waste packages that do not meet process specifications or disposal criteria. Appropriate collection or segregation may expedite the achievements of such goals. (SF-1, para 4.5)

Data on the type of radioactive waste to be processed (i.e. pretreated, treated and conditioned) or stored, as well as on material that is to be cleared or discharged at the facility or within the activity, should be collected with respect to the volume and form of the waste, the radionuclides of concern, the radioactive content, the presence of fissile materials, and other physical, chemical and pathogenic properties. Secondary waste streams that may arise from waste processing should be included.

(GSG-3, Para 4.44)

The characterization serves to provide information relevant to process control and assurance that the waste or waste package will meet the acceptance criteria for processing, storage, transport and disposal of the waste. The relevant characteristics of the waste have to be recorded to facilitate its further management. (GSR Part 5, para 4.11)

P-62:

The licensee shall use the record management system as established in P-22 for the documentation of the characteristics of every outgoing product.

Related IAEA safety standard:

The operating organization should develop and maintain a records system on the generation, processing, storage and transfer of radioactive waste (e.g. for further processing, storage or disposal), which should cover, among other aspects, the radioactive inventory, the location and characteristics of the radioactive waste, and information on its ownership, origin and place of transfer. [...]

(SSG-41, para 3.29)

2.4.8 Safety issue: Use of mobile waste processing equipment

P-63:

The licensee shall only use mobile waste processing equipment which has clearly defined, safe interfaces to the hosting facility.

Related IAEA safety standard:

In the design and safety justification for the facility, not only the facility itself but also the interfaces with other facilities and installations that may affect its safety shall be considered.

(NS-R-5 (Rev.1), para 6.3)

The operating organization shall ensure that safety related interdependences between facilities on the same site are considered. Boundary responsibilities shall be clearly specified and effective communication routes shall be established. (NS-R-5 (Rev.1), para 9.6)

P-64:

The licensee shall provide a safety case for the use of the mobile waste processing equipment. The safety case shall take into account among other things the installation, maintenance, decontamination and de-installation phases, as well as the operational phase.

Related IAEA safety standard:

The safety case should address how the principles of good engineering practice have been applied, and the operator should demonstrate in the safety case that the materials, equipment and processes foreseen for the facility or activity are well understood and that knowledge gained from similar applications confirms that these materials, equipment and processes are well suited for the intended use. (GSG-3, para 4.60)

The operator shall prepare a safety case and a supporting safety assessment. In the case of a step by step development, or in the event of modification of the facility or activity, the safety case and its supporting safety assessment shall be reviewed and updated as necessary.

(GSR Part 5, Requirement 13)

The safety case for a predisposal radioactive waste management facility shall include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility, and the managerial controls satisfy the regulatory requirements. The safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to the regulatory body that safety requirements will be met. (GSR Part 5, Requirement 14)

2.5

Safety area: Safety verification

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2.5.1 Safety issue: Contents and updating of the facility safety case

P-65:

The licensee shall provide a facility safety case and use it as a basis for continuous support of safe operation throughout the lifetime of a facility and for assessing the safety implications of changes to the facility or to operating practices.

Related IAEA safety standard:

The operator shall prepare a safety case and a supporting safety assessment. In the case of a step by step development, or in the event of modification of the facility or activity, the safety case and its supporting safety assessment shall be reviewed and updated as necessary.

(GSR Part 5, Requirement 13)

P-66:

The licensee shall ensure the facility safety case covers the facility itself, the radioactive waste, new or modified systems, structures and components and their respective safety-relevant features. The safety case shall include a description of how all the safety aspects of the site, the design, construction and operation, as well as provisions for decommissioning of the facility, and the managerial controls satisfy the regulatory requirements.

Related IAEA safety standard:

The safety case for a predisposal radioactive waste management facility shall include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility, and the managerial controls satisfy the regulatory requirements. The safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to the regulatory body that safety requirements will be met. (GSR Part 5, Requirement 14)

The safety case has to address operational safety and all safety aspects of the facility and activities. The safety case has to include considerations for reducing hazards posed to workers, members of the public and the environment during normal operation and in possible accident conditions.

(GSR Part 5, para. 5.6)

P-67:

The licensee shall provide assurance through the facility safety case that workers and members of the public are and will remain adequately protected against the hazards associated with all activities related to the processing of radioactive waste.

Related IAEA safety standard:

The safety case for a predisposal radioactive waste management facility shall include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility and the managerial controls satisfy the regulatory requirements. The safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to the regulatory body that safety requirements will be met. (GSR Part 5, Requirement 14)

The safety case has to address operational safety and all safety aspects of the facility and activities. The safety case has to include considerations for reducing hazards posed to workers, members of the public and the environment during normal operation and in possible accident conditions.

(GSR Part 5, para. 5.6)

P-68:

The licensee shall update the facility safety case to reflect

- revised or new regulatory requirements and relevant standards;
- results of the periodic safety review; and,
- results from the operational feedback programme and analysis of incidents.

Updates shall be carried out as soon as practicable and in accordance with safety significance.

Related IAEA safety standard:

The operator shall carry out periodic safety reviews and shall implement any safety upgrades required by the regulatory body following this review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility. (GSR Part 5, Requirement 16)

The safety assessment and the management systems within which it is conducted have to be periodically reviewed at predefined intervals in accordance with regulatory requirements. In addition to such predefined periodic reviews, the safety assessment has to be reviewed and updated:

- *When there is any significant change that may affect the safety of the facility or activity;*
- *When there are significant developments in knowledge and understanding (such as developments arising from research or operational experience feedback);*
- *When there is an emerging safety issue owing to a regulatory concern or an incident;*
- *When there have been significant improvements in assessment techniques such as computer codes or input data used in the safety analysis. (GSR Part 5, para. 5.12)*

2.5.2 Safety issue: Periodic safety reviews

P-69:

The licensee shall carry out a Periodic Safety Review (PSR) of the facility at regular intervals. The review shall be carried out at a frequency which shall be established by the national regulatory framework (e. g. every ten years).

Related IAEA safety standard:

The operator shall carry out periodic safety reviews and shall implement any safety upgrades required by the regulatory body following this review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility. (GSR Part 5, Requirement 16)

P-70:

The licensee shall ensure that the scope and methodology of the PSR is clearly defined and justified. The PSR shall confirm compliance with the licensing requirements. It shall also identify and evaluate the safety significance of differences from applicable current safety standards and good practices and take into account the cumulative effects of changes to procedures, modifications to the facility and the operating organization, technical developments, operational experience accumulated and ageing of SSCs.

Related IAEA safety standard:

The operator shall carry out periodic safety reviews and shall implement any safety upgrades required by the regulatory body following this review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility. (GSR Part 5, Requirement 16)

In accordance with the national regulatory requirements, the operating organization shall carry out periodic safety reviews to confirm that the licensing documentation remains valid and that modifications made to the facility, as well as changes in its operating arrangements or utilization have been accurately reflected in the licensing documentation. In conducting these reviews, the operating organization shall expressly consider the cumulative effects of changes to procedures, modifications to the facility and the operating organization, technical developments, operating experience and ageing.

(NS-R-5 (Rev.1), para 4.26)

P-71:

The licensee shall document the results of the PSR, shall submit the results to the regulatory body, and shall develop and implement an action plan for all reasonably practicable improvements to safety.

Related IAEA safety standard:

The results of the periodic safety reviews shall be presented by the operating organization to the regulatory body and shall be reflected in updates of the facility licensing documentation.

(NS-R-5 (Rev.1), para 9.69)