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TABLE OF CONTENTS

| | | |
|----------|---|-----------|
| 3 | MANAGEMENT SYSTEM | 6 |
| 3.1 | PARTICULAR ASPECTS OF MANAGEMENT PROCESSES | 7 |
| 3.2 | QUALITY ASSURANCE IN IMPLEMENTATION OF THE INTEGRATED LILW REPOSITORY PROJECT | 9 |
| 3.2.1 | <i>Implementation of the integrated LILW repository project (PVP II, PVP III)</i> | <i>10</i> |
| 3.2.2 | <i>LILW repository management system following the completion of construction (trial and regular operation phase)</i> | <i>11</i> |
| 3.3 | COMMON CHAPTERS OF THE MANAGEMENT SYSTEM FOR THE INTEGRATED LILW REPOSITORY PROJECT OR THE TRIAL AND REGULAR OPERATION OF THE LILW REPOSITORY | 13 |
| 3.3.1 | <i>Management policy.....</i> | <i>13</i> |
| 3.3.2 | <i>Organisation.....</i> | <i>14</i> |
| 3.3.3 | <i>Repository personnel.....</i> | <i>15</i> |
| 3.3.4 | <i>Management system.....</i> | <i>16</i> |
| 3.3.5 | <i>Graded approach.....</i> | <i>16</i> |
| 3.3.6 | <i>Planning.....</i> | <i>17</i> |
| 3.3.7 | <i>Management system documentation and records</i> | <i>17</i> |
| 3.3.8 | <i>Resources</i> | <i>19</i> |
| 3.3.9 | <i>Safety culture</i> | <i>20</i> |
| 3.3.10 | <i>Processes for achieving the objectives, providing funds and supplying products.....</i> | <i>21</i> |
| 3.3.11 | <i>Supervision of external contractors and suppliers</i> | <i>21</i> |
| 3.3.12 | <i>Measurements, assessment and improvements.....</i> | <i>23</i> |
| 3.3.13 | <i>Management of non-compliance and corrective/preventive actions.....</i> | <i>24</i> |
| 3.4 | CONCLUSIONS | 25 |
| 3.5 | REFERENCES | 26 |

ABBREVIATIONS AND TERMS

ARAO – Agency for Radwaste Management

EBA – Electronic document management system of the company EBA d.o.o., Ljubljana

IAEA – International Atomic Energy Agency

NEK – Krško nuclear power plant (Krško NPP)

LILW – Low- and intermediate-level radioactive waste

PVP II – LILW repository project management manual, Phase II

QC – Quality control

QA – Quality assurance

PDFN – Programme of work and financial plan

RW – Radioactive waste

SNSA – Slovenian Nuclear Safety Administration

ZVISJV – Ionising Radiation Protection and Nuclear Safety Act

The terms used in this document shall have the same meaning as in the ZVISJV and the implementing regulations adopted on the basis of that act. The following terms shall also be used:

Safety culture comprises the characteristics and behaviour within an organisation or among individuals that place greatest emphasis on protection and safety and that accord them the priority that corresponds to their importance. In relation to radiation or nuclear safety, safety culture relates to the personal commitment and responsibility of everyone involved in any activity that affects the operation and safety of a radiation or nuclear facility. The open exchange of information, which includes the unrestricted discussion of safety and other associated issues, the prevention of self-sufficiency, a commitment to completeness, personal and collective responsibility, and an increase in the level of radiation or nuclear safety, are key parts of the safety culture.

Management system means the sum of interconnected and intertwined elements enabling the uninterrupted and efficient operation of an organisation. It establishes policy and objectives, and facilitates efficient and effective achievement of objectives. The management system combines all requirements concerning safety, health, the environment, physical protection, quality and cost-effectiveness.

Quality assurance means all planned and systematically performed human activities or actions that ensure an acceptable level of confidence that a specific procedure, organisation of a measure or item of ionising radiation protection or nuclear safety equipment, or any component thereof, has been executed in a satisfactory manner and in accordance with the agreed standards. Quality assurance must also include quality verification procedures.

Process is the sum of interconnected or mutually influencing activities performed to achieve a specific objective. A process can be any activity or action involving an input that is then changed into an output; this means that processes are almost all activities and actions that lead to the creation of a product or service.

Procedure is the prescribed manner of performing an activity or process.

Operational procedures are precise written procedures for the operation of a radiation or nuclear facility.

3 MANAGEMENT SYSTEM

A successful and effective management system is an obligation and an indispensable organisational tool for achieving the objectives set and assuming responsibility for the results of one's work. This applies specifically to an organisation that handles radioactive waste and operates a nuclear or radiation facility. Such an organisation is obliged to systematically provide for the high-quality and safe performance of the required activities in a way that is acceptable to human health and the environment, and to ensure that it operates in a public and transparent way.

The legal requirements for the management system are laid down in Article 63 of the ZVISJV [1], which requires an investor or operator of a radiation or nuclear facility to manage the facility safely and in accordance with the provisions of the Act. The operator of a radiation or nuclear facility shall also establish, implement, evaluate and continually improve the management system, which incorporates all requirements regarding safety, health, the environment, physical protection, the security of information systems and data, quality and cost-effectiveness, so that the safety aspects are given due weight in all activities performed by the operator of the radiation or nuclear facility. The requirements are further defined in the JV5 rules [2], which state that the investor or operator of a radiation or nuclear facility shall establish, implement and continuously improve an effective and integrated management system so as to ensure radiation and nuclear safety.

Chapter 3 of the PS 1.03 Practical Guidelines [3] sets out the content of the Safety Report for the Low- and Intermediate-Level Radioactive Waste (LILW) Repository in relation to the management system. It envisages the presentation of particular aspects of the management processes, quality assurance and safety culture. The chapter includes a description and assessment of safety management and of the procedures and processes introduced to ensure adequate control of all safety aspects in all periods of the repository. The management system must be prepared in accordance with Chapter V of the JV5 rules, Articles 52–74 of which set out the requirements for the management system of an investor or operator of a radiation or nuclear facility. The PS 1.03 Practical Guidelines also state that the repository management system, the roles of the organisations charged with assessing the safety of the repository, and any safety advisory boards outside the organisations advising the operator's management must be presented. The aim of the chapter is to demonstrate that the operator's management is able to meet its responsibilities regarding repository safety throughout all periods of the repository.

Due regard is also given to the following IAEA documents:

- IAEA document SF-1 [4] sets out the safety principles, with Safety Principle 3 describing leadership and management for safety.
- The safety requirements for the management system are set out in IAEA document GS-R-3 [5].
- The revised safety requirements for the management system are set out in IAEA document GSR Part 2 [6].
- The safety guidelines on how to meet the safety requirements for the management system are set out in IAEA document GS-G-3.1 [7].

- The safety guidelines on how to meet the safety requirements for the management system for technical services and radiation safety services are set out in IAEA document GS-G-3.2 [8].
- The safety guidelines on how to meet the safety requirements for the management system for the processing, handling and storage of RW are set out in IAEA document GS-G-3.3 [9].
- The safety guidelines on how to meet the safety requirements for the management system for the disposal of RW are set out in IAEA document GS-G-3.4 [10].
- The safety guidelines on how to meet the safety requirements for the management system for nuclear installations are set out in IAEA document GS-G-3.5 [11].

As the future operator of the LILW repository, ARAO has established and introduced an integrated management system that also includes a management system for the LILW repository nuclear facility. It regularly assesses the facility and makes continuous improvements based on the findings of the assessment. The ARAO management system has been set up as a single integrated management system that brings together the areas of quality, environmental management, health and safety at work, nuclear and radiation safety, protection, human and organisational factors, social relations and economics. The management system describes how to ensure that the organisation can achieve all the set objectives safely, effectively and efficiently. It is implemented as a system of management, main, support and external processes through which ARAO realises its mission, ensures that services are of high quality, ensures human health and safety and environmental protection, satisfies interested parties and realises the planning policies and thereby the interests of the state, stakeholders and the social environment in which ARAO operates.

The annual verification of compliance of the management system under the requirements of the ISO 9001 standard is performed by the [SIQ \(Slovenian Institute of Quality and Metrology\)](#). In 2018 ARAO successfully passed an external assessment of the management system under the requirements of the ISO 9001:2015 standard, into which the requirements of the JV5 rules [2] have been incorporated. Compliance of the management system with the JV5 rules is shown in the Annex to the ARAO Rules of Procedure (PV1).

3.1 PARTICULAR ASPECTS OF MANAGEMENT PROCESSES

The ARAO management system is incorporated into the ARAO Management Rules of Procedure [12], which documents the mission, vision, strategic objectives, quality and environmental management policy and the safety policy as formulated by the highest management level at ARAO. The documents have been published on the ARAO website (<http://www.arao.si/>).

In order to ensure the highest possible degree of organisational and work flexibility, ARAO is organised as a vertical and horizontal internal network, i.e. into a system of interconnected processes. The processes are defined on the basis of the operational objectives of ARAO, and include, as required, the members of various vertical organisational units. At the Agency, a distinction is made between management, main, support and external processes (Figure 3-1).

All processes are planned within the PDFN (programme of work and financial plan) for a specific programming year. The process indicators defined in the process definitions are checked against specific aspects (nuclear and radiation safety, environmental aspects, health and safety at work, fire safety, quality, protection and economics) by means of control and supervisory measurements, tests, reviews and analyses.

The results of the work are regularly reported to the director’s committees, where any dilemmas are directly resolved and guidelines given for future work. The results of the PDFN are documented at the end of the year in the annual report and the ARAO sustainability report.

Internal assessments are also performed as a form of self-assessment of the management system. The systemic analysis of results performed by the process heads and heads of services and the results of the ARAO internal assessment and the results of any assessment of suppliers is addressed on an annual basis at the management review. ARAO management therefore identifies any opportunities for improvements and adopts decisions on the future implementation of the proposed improvements.



Figure 3-1: Presentation of processes within the ARAO management system Independent review of the ARAO management system comprises external assessments by the SIQ.

| | |
|----------------------------------|---------------------------------|
| VODSTVENI PROCESI | MANAGEMENT PROCESSES |
| VODENJE ARAO | MANAGEMENT OF ARAO |
| GLAVNI PROCESI | MAIN PROCESSES |
| NAČRTOVANJE ODLAGALIŠČA NSRAO | PLANNING OF THE LILW REPOSITORY |
| RAVNANJE Z INSTITUCIONALNIMI RAO | INSTITUTIONAL RW MANAGEMENT |

| | |
|---|--|
| GJS DOLGOROČNEGA NADZORA IN VZDRŽEVANJA ODLAGALIŠČ RUDARSKE IN HIDROMETALURŠKE JALOVINE | PUBLIC UTILITY SERVICE LONG-TERM MONITORING AND MAINTENANCE OF REPOSITORIES OF MINING AND HYDRO-METALLURGICAL TAILINGS |
| NAČRTOVANJE IN PODPORA DELEŽNIKOM | PLANNING AND SUPPORT FOR STAKEHOLDERS |
| RADIOLOŠKI NADZOR IN VARSTVO PRED SEVANJI | RADIATION MONITORING AND PROTECTION AGAINST RADIATION |
| PODPORNI PROCESI | SUPPORT PROCESSES |
| MEDNARODNO SODELOVANJE IN RAZVOJ | INTERNATIONAL COOPERATION AND DEVELOPMENT |
| KOMUNIKACIJSKE DEJAVNOSTI | COMMUNICATION ACTIVITIES |
| SISTEMSKA PODPORA | SYSTEM SUPPORT |
| ZUNANJI PROCESI | EXTERNAL PROCESSES |
| STORITVE PROJEKTIRANJA, SERVISIRANJA, PREGLEDOV, MONITORINGOV, MERITEV, ... | DESIGN SERVICES, SERVICING/REPAIRS, REVIEWS, MONITORING, MEASUREMENTS, ETC. |
| ODJEMALCI – INTERESI, POTREBE, ZAHTEVE | CONSUMERS - INTERESTS, NEEDS, REQUIREMENTS |
| ODJEMALCI – ZADOVOLJSTVO, IZPOLNITEV PRIČAKOVANJ, PRIPADNOST | CONSUMERS - SATISFACTION, FULFILMENT OF EXPECTATIONS, LOYALTY |

3.2 QUALITY ASSURANCE IN IMPLEMENTATION OF THE INTEGRATED LILW REPOSITORY PROJECT

We have summarised the approach to quality assurance within the ARAO management system from the IAEA requirements (GSR Part 2) [6] or the JV5 requirements [2]. Development of the management system is viewed as the integration of individual requirements relating to health, the environment, protection, quality, cost-effectiveness and social aspects; in order to prevent any negative impact of other requirements on radiation or nuclear safety, these requirements are not addressed separately from radiation or nuclear safety requirements. The single management system is applied to all processes performed by ARAO, including activities performed by contractual providers (Figure 1). The safety aspects must be taken into account as a matter of priority in all decisions.

In ensuring radiation or nuclear safety, a graded approach is permitted, which means that greater attention is given to important characteristics (i.e. they are designed or described in greater detail or more extensively) and less attention is paid to less important characteristics (i.e. they are designed or described in less detail). It should be emphasised at this point that the dimensions of technical damage are connected to social damage and the impacts of undesirable events on the public.

The second-level management system for the integrated LILW repository project is set out in the PVP II Project Management Manual [13]. The manual defines the system of planning, management and supervision of the implementation of activities for the LILW repository project in Phase II, i.e. from the completed siting process up to the acquisition of a construction permit. The manual also defines the link to external stakeholders, i.e. the representative of the founder (Ministry of Infrastructure as the line ministry), the other ministries/state institutions involved, and the users of the repository services (GEN Energija, Krško NPP).

The manual has been coordinated with the ARAO Management Rules of Procedure and defines in greater detail the particular aspects of the LILW repository project. Owing to the special status of this project in comparison with other projects at ARAO, the term “integrated LILW repository project” is used in this manual as well as in the ARAO Management Rules of Procedure when referring to this project (Figure 3-2). Many projects at ARAO are carried out

as part of an integrated project; therefore, in these cases their substantive, organisational and methodological aspects are subordinate to the “integrated project”.



Figure 3-2: Presentation of the integrated repository project as part of the “Planning of the LILW repository” process [14]

| | |
|-----------------------------|-------------------------------|
| ODLAGANJE NSRAO | LILW DISPOSAL |
| Umestitev | Placement/siting |
| Načrtovanje | Planning |
| Gradnja | Construction |
| Poskusno obratovanje | Trial operation |
| Redno obratovanje | Regular operation |
| Zapiranje odlagališča | Closure of the repository |
| Dolgoročni nadzor | Long-term monitoring |
| CELOVIT PROJEKT ODLAGALIŠČA | INTEGRATED REPOSITORY PROJECT |

3.2.1 IMPLEMENTATION OF THE INTEGRATED LILW REPOSITORY PROJECT (PVP II, PVP III)

The Resolution on the National Programme for Radioactive Waste and Spent Nuclear Fuel Management defines the tasks required to ensure the permanent and safe resolution of the issue of radioactive waste and spent nuclear fuel management regardless of whether Slovenia remains a nuclear state after the end of the operating lifetime of Krško NPP [15]. The construction of the LILW repository must be treated as a key environmental project of the national programme, since a site acquired and repository constructed on time ensures effective protection of the natural environment against the uncontrolled discharge of radioactive materials.

To this end, the entire project comprises four key phases:

- I. Siting of the LILW repository (30 November 2004¹ to 30 December 2009)
- II. Planning of the repository
- III. Construction of the repository
- IV. Trial operation

The LILW repository siting phase concluded with the adoption of the Decree on the detailed plan of national importance for a low- and intermediate-level radioactive waste repository at Vrbina, Municipality of Krško by the Slovenian government on 30 December 2009 [16].

¹ The date that the Slovenian government adopted the Programme for the Preparation of the National Site Development Plan.

Starting points for the subsequent phases were prepared as part of the first phase of the project, including:

- approval of the solution using disposal units in the form of a silo, which was adopted as the most acceptable of the three alternatives following a multilateral assessment of the acceptability of the activity affecting the environment with a comparison of the alternatives from five aspects: functional, safety, environmental, spatial and economic aspects, as well as the aspect of acceptance within the local environment;
- the preliminary design, which defines the technical solution;
- the pre-investment plan, which provides the baseline assessments regarding the required sources for realisation of the project.

The basic purpose of the management system for the repository project is to ensure that nuclear safety always has the highest priority throughout the entire lifecycle of the nuclear facility [13].

The following are taken into account in connection with this:

- the applicable domestic legislation and international regulations and standards that must be observed in relation to the project;
- the specific nature of the requirements for a nuclear facility, including quality control and the provision of a high safety culture at all phases of the project;
- the simultaneous implementation of preparations (tender documentation, etc.) during Phase III in order to optimise the duration of the project as a whole;
- contents from the Project Management Rules of Procedure for the siting of the LILW repository (NSRAO – DLN – POS 02/09), Phase I, which are also of relevance to Phase II.

The management system for the project shall also, where relevant, include the specific requirements addressed in the ARAO Management System Rules of Procedure, and therefore constitute an inseparable part thereof. Under specific points, the requirements are included as text or make reference to the reference documents of the ARAO Rules of Procedure.

3.2.2 LILW REPOSITORY MANAGEMENT SYSTEM FOLLOWING THE COMPLETION OF CONSTRUCTION (TRIAL AND REGULAR OPERATION PHASE)

Under the ARAO management system, tests of the operation of the constructed repository will be performed during the trial operation phase in order to verify and define the conformity of the constructed devices with the approved design solutions and the required design conditions and, at the same time, the adequacy of the design solutions and operating procedures, which address the use of these solutions, depending on the desired functions of SSCs.² Trial operation also covers abnormal operating conditions (anomalies) and accidents.

² IAEA, SSG-29, paragraph 6.45;

A trial operation programme has been prepared to that end; it will be an annex to the application for the acquisition of approval for the commencement of trial operation of the LILW repository.³ As the content of the programme is not defined in the regulations and the important reference documents⁴, the programme has been drafted in accordance with the PS 1.03 Practical Guidelines [3], the Management System for Facilities and Activities, Safety Requirements No GS-R-3 (IAEA requirements) [5], the Management System for Nuclear Installations, Safety Guide No GS-G-3.5 (Appendix VI, IAEA recommendations) [11] and Near Surface Disposal Facilities for Radioactive Waste, Specific Safety Guide No SSG-29 (IAEA recommendations) [17].

Trial operation of the repository is further performed by means of acceptance procedures, procedures for the establishment of compliance with the acceptance criteria and for the recording and disposal of LILW drawn up based on the RW management programme.⁵ The transfer of responsibilities during the construction and trial operation phases shall be carried out in accordance with the applicable provisions of the ZGO-1 for this area [18][19].

During the regular operation phase (IBE NRVB-5X/23), which also includes the standby phase (IBE NRVB-5X/24), the repository will operate, within the framework of the applicable management system, in accordance with the operational limits and conditions. All reference documentation governing the operation and the standby phase will also form the basis for the implementation of trial operation in accordance with the IBE NRVB---5X1022 reference document and, to a reasonable extent, for implementation of the closure of the repository in accordance with the IBE NRVB---5X1025 reference document.

The management system for regular operation will be revised on the basis of the JV9 rules [20] and of Chapter 9 of the PS 1.03 Practical Guidelines (Content of the safety report for the low and intermediate-level waste repository, Version 1, SNSA, 10 July 2012 (Operation)) [3]. Due regard shall also be paid to Leadership and Management for Safety No GSR Part 2 (IAEA requirements), the JV5 rules, the Management System for Nuclear Installations, Safety Guide No GS-G-3.5 (Appendix VII, IAEA recommendations) and Near Surface Disposal Facilities for Radioactive Waste, Specific Safety Guide No SSG-29 (IAEA recommendations) in the production and revision process.

The repository management and services shall be responsible for the trial and regular operation of the repository. The responsibilities of individual entities involved in trial operation during the trial and regular operation phases shall be transferred in accordance with the provisions of the programme for the management of changes at the repository (IBE NRVB---5X1027).

³ JV5 rules, Article 26, first paragraph, point 2;

⁴ The JV5 and JV9 rules do not define the trial operation programme, and IAEA document SSR-5 and the U.S. NRC 10CFR61 document do not address trial operation.

⁵ The RW management programme is the investor's/operator's basic programming document and an independent reference document (JV5, Article 40, first paragraph, point 18).

With the acquisition of the operating permit for the repository, ARAO's responsibilities shall become the responsibilities of the repository operator.⁶

ARAO monitors and will continue to monitor its own (CSRAO) and international operating experience in connection with repositories, new findings acquired from research and development, amendments to regulations and standards, and instructions from manufacturers, their associations and international organisations, and systematically evaluate and apply them.⁷

The operating experience feedback programme ensures that occurrences at the repository are identified, recorded, reported to appropriate decision-making levels and examined at ARAO, and that appropriate corrective measures are adopted to prevent similar occurrences from recurring. The programme also regulates the method by which the regulatory body is notified. The programme has been drawn up in accordance with the requirements of Article 7 of the JV9 rules.

ARAO will implement the operating experience and operating indicators feedback process in accordance with the IBE NRVB---5X1028 operating experience feedback programme.

A document defining the management system in accordance with the applicable legislation, standards and IAEA guidelines and recommendations will be enclosed with every application for a specific phase of the integrated repository project or the trial or regular operation of the repository. The common chapters of the document are stated in the next chapter.

3.3 COMMON CHAPTERS OF THE MANAGEMENT SYSTEM FOR THE INTEGRATED LILW REPOSITORY PROJECT OR THE TRIAL AND REGULAR OPERATION OF THE LILW REPOSITORY

3.3.1 MANAGEMENT POLICY

The management policy for the LILW repository project or for trial and regular operation shall follow the policy defined by ARAO in its Management Rules of Procedure.

Safety policy is a key component of the management policy and gives clear priority to ensuring safety above all other activities on the project or the future nuclear facility.

All heads, starting with management staff, shall work in accordance with the principle that the final and basic objective of protecting human beings and the environment from the harmful effects of ionising radiation is achieved primarily by:

- meeting the requirements of all the adopted standards;
- ensuring that all heads within the organisation develop and retain skills and knowledge for understanding the risks of ionising radiation and the possible

⁶ ZVISJV, Article 3, first paragraph, point 72;

⁷ In accordance with the first paragraph of Article 6 of the JV9 rules.

consequences, including an understanding of the operation of technology and people that reduce these risks to an acceptable level;

- ensuring that resources are in place in an adequate quantity and scope, including for the protection of future generations;
- ensuring that all expert analyses and research are safely implemented.

Heads must continuously demonstrate leadership for achieving safety, and a commitment to safety, chiefly by:

- establishing, promoting and observing an organisational approach to safety;
- informing colleagues that safe operation is conditional upon the interaction of people, technology and organisation;
- establishing expectations regarding conduct and promoting good behaviour and a safety culture;
- ensuring that their leadership includes the development of personal and institutional values and expectations regarding the achievement of business and safety objectives based on their decisions, statements and actions.

Management shall be responsible for establishing, implementing, maintaining and improving the system for the purpose of ensuring safety.

Safety must never be compromised in pursuit of satisfying stakeholders' wishes.

3.3.2 ORGANISATION

Organisation on the LILW repository project comprises individuals and organisational units whose operations are oriented towards the project's objectives. It is documented in greater detail in Chapter 4 of the PVP II and ensures that all requirements for the future safe and reliable operation of the repository and an adequate response to an emergency are taken into account in Phase II and in preparations for Phase III. The supervisory steering group shall regularly evaluate the effectiveness of the organisation [13].

During the trial and regular operation phases, the repository will operate as an independent organisational unit of ARAO (LILW repository sector).

The organisation of repository operation is shown in Figure 3-3. All the repository services and organisational units shall take part in operation and, in so doing, shall act in collaboration with and with the assistance of existing ARAO services [21].

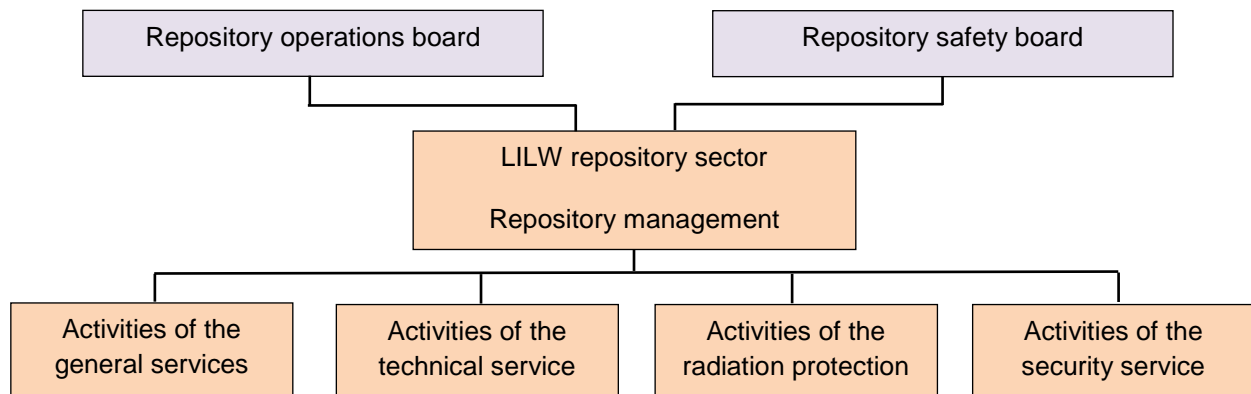


Figure 3-3: Organisation of repository operations

The following existing ARAO services shall therefore be involved in operations and in the monitoring of operations:

- Engineering sector (ARAO);
- QA/QC service (ARAO);
- Radiation protection service (ARAO).

The radiation protection service reports directly to the ARAO director.

As the ARAO director's advisory bodies, the following bodies are involved in the monitoring of operations:

- Repository operations board;
- Repository safety board.

3.3.3 REPOSITORY PERSONNEL

The roles of ARAO sectors and services in the operations of the repository shall be defined by the ARAO organisational regulations. The roles of organisational units in implementing specific groups of repository activities and of supervisory bodies are outlined in the reference document [21]. A systematic analysis will be conducted to determine the number of employees and the qualifications they require for ensuring nuclear safety. A ten-year plan of staff recruitment in the areas important to nuclear safety will be drawn up in good time. The plan will be revised at least every three years. Every planned change to the number of employees that could have an important impact on nuclear safety shall be justified in advance, and evaluated after the change has been introduced. ARAO will have sufficient properly trained personnel who are familiar with the repository design bases of the nuclear facility, understand the actual design and operation of the facility in all its states, prepare project briefs and acceptance criteria for the outsourcing of nuclear safety-related works to subcontractors, supervise the execution of these works, and assess them after acceptance.

In Phase II of the LILW repository project, the adequate staff is defined in Chapter 4 of the PVP II manual.

All persons actively participating in the trial and regular operation activities at the repository site must have completed the training provided by ARAO. The training also covers topics in

the fields of radiation protection, health and safety at work, fire protection, measures in response to emergencies, and physical protection.⁸

Persons of key significance for repository operation shall be qualified and trained in accordance with general provisions and the provisions of Chapter IV.3 of the JV4 rules [22].

3.3.4 MANAGEMENT SYSTEM

The integrated management system for the LILW repository project defined in the PVP II manual is connected in terms of its content with the ARAO Management Rules of Procedure and is regularly audited and continuously improved in tandem with the rules.

The management system ensures that the requirements of Slovenian legislation and international requirements and standards, which also include specific requirements for the nuclear area covered by the LILW repository, are consistently observed in relation to all project products. These specific requirements are explicitly highlighted in Chapters 6.1 and 6.2 of the PVP II manual.

The highest management level at ARAO is ultimately responsible for all aspects of the management system. The supervisory steering group, which reports to the design board and thereby to ARAO management, has a specific supervisory role in the LILW repository project.

The management system ensures that the nuclear safety of the (future) facility is achieved and continuously improved, and through its consistent implementation prevents other aspects, including health, the environment, protection, quality and economics, from being considered separately from nuclear safety aspects. This enables the integration of quality aspects important to the nuclear facility and the mutual coordination of their requirements.

All activities important to the safe management and operation of the repository shall be carried out in accordance with the specifications of the processes and sub-processes and particularly with the written procedures required under the JV7 rules [23]. The management system will also incorporate documents arising from general requirements concerning repository operation (e.g. Rules of Procedure in accordance with ISO 9001, Chapter V of the JV5 rules and associated documents, such as: Safety declaration with risk assessment, Fire rules, Evacuation plan, RW management programme, etc.). The list of envisaged administrative and operational procedures of organisational units in relation to the operation of the LILW repository is given in the reference documentation [21].

3.3.5 GRADED APPROACH

The management system pays due regard to the principle of the graded approach, which enables the appropriate use of available resources for products and services as well as for processes connected with radiation or nuclear safety.

Accordingly, the importance and complexity of an individual activity and its results, its dangers and any possible negative impacts and consequences arising from its incorrect implementation or adverse results shall be taken into account in the planning and implementation of activities

⁸ IAEA, SSG-29, paragraph 6.51;

in Phase II of the LILW repository project. Potential risks in relation to safety, health, protection, quality and economic elements shall be taken into account.

The criteria and requirements of the graded approach during trial and regular operation of the repository by which the available resources are to be used shall be documented and incorporated into the management system. Due regard will have to be taken into account in this regard [2]:

- the importance and complexity of an individual process or activity;
- the possible dangers, safety risks and radiation impacts in the implementation of processes or activities;
- possible negative impacts on and consequences for safety in the event of incorrect implementation of a process or activity or an unanticipated event during implementation.

3.3.6 PLANNING

During the planning of the realisation of products, services or processes connected with radiation or nuclear safety, input requirements shall be identified and defined in the appropriate manner in the areas of safety, quality, the environment, health and safety at work, as well as other requirements relevant for the project product, in accordance with the description of the process of the planning of the implementation of the integrated project, i.e. operation of the repository. The planning inputs must contain the following in an appropriate form:

- the quality requirements as prescribed by legislation, regulations and standards concerning the project product;
- the safety requirements as prescribed by legislation, safety regulations and standards concerning the project product;
- the environmental requirements as prescribed by legislation, regulations and environmental standards concerning the project product;
- the health and safety at work, fire protection, protection, etc. requirements as prescribed by legislation, regulations and standards concerning the project product.

3.3.7 MANAGEMENT SYSTEM DOCUMENTATION AND RECORDS

The entire management system is structured by level. The management system documents make reference, where relevant, to other organisational and technical rules and instructions, legislation and contracts. The management system documents are structured into three levels depending on whether their requirements relate to the entire system, an individual process within the system or an individual sub-process/activity (**Figure 3-4**).

The integrated electronic document system is managed using the [EBA DMS](#) [24] software tool.

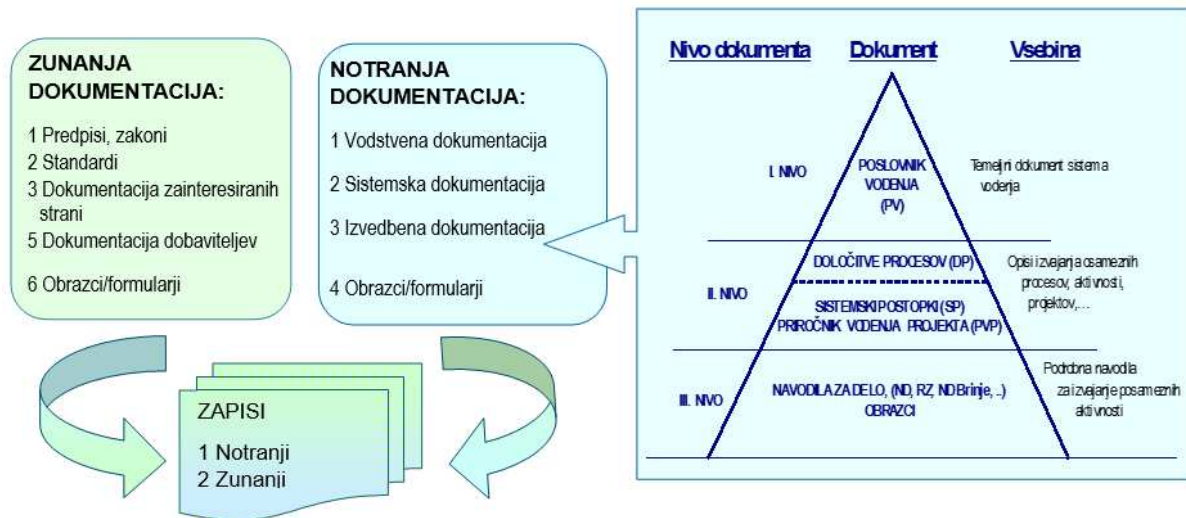


Figure 3-4: Types of documentation and their connection to the documentation pyramid of the ARAO management system

| | |
|---|--|
| ZUNANJA DOKUMENTACIJA: | EXTERNAL DOCUMENTATION: |
| 1 Predpisi, zakoni | 1 Regulations, laws |
| 2 Standardi | 2 Standards |
| 3 Dokumentacija zainteresiranih strani | 3 Documentation of interested parties |
| 5 Dokumentacija dobaviteljev | 5 Supplier documentation |
| 6 Obrazci/formularji | 6 Forms |
| NOTRANJA DOKUMENTACIJA: | INTERNAL DOCUMENTATION: |
| 1 Vodstvena dokumentacija | 1 Management documentation |
| Sistemska dokumentacija | System documentation |
| 3 Izvedbena dokumentacija | 3 Implementing documentation |
| 4 Obrazci/formularji | 4 Forms |
| ZAPISI | RECORDS |
| 1 Notranji | 1 Internal |
| 2 Zunanji | 2 External |
| Nivo dokumenta | Document level |
| Dokument | Document |
| Vsebina | Contents |
| I. NIVO | LEVEL I |
| POSLOVNIK VODENJA (PV) | MANAGEMENT RULES OF PROCEDURE (PV) |
| Temeljni dokument sistema vodenja | Basic management system document |
| II. NIVO | LEVEL II |
| DOLOČITVE PROCESOV (DP) | DEFINITION OF PROCESSES (DP) |
| SISTEMSKI POSTOPKI (SP) | SYSTEM PROCEDURES (SP) |
| PRIROČNIK VODENJA PROJEKTA (PVP) | PROJECT MANAGEMENT MANUAL (PVP) |
| Opisi izvajanja posameznih procesov, aktivnosti, projektov, ... | Description of performance of individual processes, activities, projects, etc. |
| III. NIVO | LEVEL III |
| NAVODILA ZA DELO (ND, RZ, ND Brinje, ...) | WORK INSTRUCTIONS (ND, RZ, ND Brinje, etc.) |
| OBRAZCI | FORMS |
| Podrobna navodila za izvajanje posameznih aktivnosti | Detailed instructions for performing specific activities |

The management system for the LILW repository project shall be supplemented with the ARAO Management System Rules of Procedure, thereby documenting all the main points (the chapters of the PVP II manual that discuss them in detail are mentioned in individual indents):

- statement on the policies and objectives of management (LILW repository project management manual 2F, NSRAO-PVP-001-01, and the chapter titled "Model of key project processes" ONSRAO 2F, NSRAO-PVP-002-00);

- a description of the management system (chapter titled “Description of the management system for the repository project”, NSRAO-PVP-006-01);
- description of the organisational structure of the project (chapter titled “Descriptions of key roles”, NSRAO-PVP-004-00);
- definition of the responsibilities, authorisations and interactions between the management, implementation and evaluation of individual activities (chapters titled “Descriptions of key roles”, NSRAO-PVP-004-00, and “Support processes for Phase 2 of the integrated LILW repository project”, NSRAO-PVP-005-01);
- description of links with external institutions;
- description of processes in the implementation of Phase 2 of the LILW repository project (chapter titled “Support processes for Phase 2 of the integrated LILW repository project”, NSRAO-PVP-005-01);
- a description of how individual activities are prepared, reviewed, implemented, documented, verified and improved (Chapters 3 to 7 of the LILW repository project management manual, 2F).

The management system documentation for the LILW repository project shall be written in a way that can be understood by all those who use it, and individual documents shall be valid, identifiable and available to everyone involved. Documents must be valid, readable, readily identifiable and easily available in the place in which they are to be used. All relevant project management system documents are available in electronic format on the server, in accordance with Chapter 5 of the PVP II manual.

Written procedures are an integral part of the management of the trial or regular operation of the repository as controlled documentation for the implementation of processes and controlled records of activities, in accordance with Article 59 of the JV5 rules. Radioactive waste shall be managed in accordance with the written procedures defined in the annexes to the JV7 rules [23].

To this end, a document titled “Forms and lists of procedures and instructions” has been drawn up as part of the reference documentation [25].

3.3.8 RESOURCES

ARAO management shall provide the resources (personnel, infrastructure, working environment, information, knowledge, suppliers and financial resources) to the extent required for implementation of the planned activities and for the establishment, implementation, assessment and continuous improvement of the management system.

The management of the financial resources for implementation of Phase II of the LILW repository project is defined in Chapter 7 of the PVP II manual [13].

The provision of resources for other activities relating to the implementation, assessment and continuous improvement of the management system is defined in the ARAO Management System Rules of Procedure [12].

3.3.9 SAFETY CULTURE

ARAO management shall foster and support a high safety culture through a system of continuous improvement by:

- managing potential events;
- ensuring that personnel have the required skills;
- ensuring that the conditions are in place for the transfer of information (knowledge, expectations, procedures);
- supporting individuals and departments so that they are able to perform their tasks successfully and in line with the safety requirements;
- fostering a positive attitude to learning and promoting critical thinking;
- continuously attending to the development and improvement of safety culture [26].

ARAO management has defined the quality and environmental management policy, the safety policy, the information security policy, the protection culture and the safety culture in a series of written statements. The policies are contained in annexes to the ARAO Management Rules of Procedure [12]. Employees as well as external contractors have been familiarised with them so that they can understand the operator's expectations.

ARAO's approach to the formation of a safety culture and to the raising of safety awareness is based on communication, the prescribed systemic and operational procedures, compliance with the legislative and normative framework, and education and training. Key information flows through narrow, expanded and technical committees. Access to and communication with process heads is enabled and mandatory at the daily level. The appointed responsible persons (fire safety, health and safety at work, safety adviser for the transport of dangerous goods, etc.) work with process heads and have direct access to and communication with the ARAO director. The raising of the safety culture at ARAO is achieved as far as possible through a programme of continuous professional staff training and advanced training.

The safety culture at ARAO is monitored by means of observation of the behaviour of employees and external contractors. Important information is documented. ARAO employees obtain this information through mutual contact and internal communication in the course of the performance of the annual programme of work; this includes observations arrived at in the course of communication with external contractors that could affect nuclear and/or radiation safety. Employees may send important information on safety culture directly to the head of the QA/QC service, which then forwards the information gathered to ARAO management. On the basis of an assessment, the ARAO director may directly order additional measures to improve the safety culture or address the gathered information once a year at the ARAO management review.

Sampling-based review gives us an additional insight into the safety culture of our own organisation or of an organisation with which we work (review of compliance with legislative requirements, health and safety at work requirements, assignment of responsibilities, management policy, instructions for conduct, procedures for the assignment and qualifications of the workforce, procedures for analysing emergencies, documented training with a particular emphasis on safety).

Self-assessment of the safety culture is performed using our own questionnaires and an analysis of the results (last performed in 2018). We have addressed the results of the assessment and self-assessment at the ARAO management review. Recommendations made on the basis of an analysis of the results at the management review are being implemented.

3.3.10 PROCESSES FOR ACHIEVING THE OBJECTIVES, PROVIDING FUNDS AND SUPPLYING PRODUCTS

Processes necessary for achieving the objectives, providing funds for the fulfilment of all the requirements, and the supply of products in Phase II of the LILW repository project are defined in Chapter 5 of the PVP II manual, where their mutual impacts are also identified [13].

The following topics are consistently included in the definition of processes in Chapter 5 from the point of view of the management system for Phase II of the project:

- project administration and management;
- management of products, documentation and records;
- risk management;
- procurement procedures;
- change management;
- communication on the project;
- planning of project implementation;
- supervision of project implementation.

The supervisory steering group monitors the success of implementation of project-related processes.

Processes not specifically defined in this manual shall be carried out in accordance with the ARAO Management System Rules of Procedure, which also define the control of documentation for the implementation of processes, change and document revision management, and the management of records [12].

3.3.11 SUPERVISION OF EXTERNAL CONTRACTORS AND SUPPLIERS

The management system in Phase II of the LILW repository project defines the requirements that must be met by external contractual providers and suppliers in terms of both the management system and the legislation and standards specific to the repository as a nuclear facility.

Supervision of external contractors and suppliers is defined in greater detail as part of the supply process, Chapter 5 of the PVP II manual [13].

As the operator of the repository, ARAO retains responsibility for all the works contractually performed on its behalf by external contractors; the supervisory steering group is therefore responsible for supervising processes and activities on a process-by-process basis even if they are partly or fully performed by contractual providers.

External contractors that assume implementation of completed activities or entire processes on the LILW repository project must have a documented management system in place that demonstrates their capacity to implement the requirements referred to in Chapters 6.1 and 6.2 of the PVP II manual [13].

ARAO assesses and selects contractors or suppliers in accordance with criteria determined in advance. Contractors and suppliers are selected under public procurement procedures that ensure that the goods and services supplied comply with the regulatory requirements [27]. The procurement requirements are laid down by the public procurement head on the basis of the need for implementation of specific activities. The public procurement head performs the procurement process or identifies the need for a procurement order to be issued. Public procurement is carried out in accordance with regulations and internal requirements that are mutually coordinated and that cover:

- a precise definition of the goods/services being ordered;
- the quality characteristics, acceptance criteria and other information determining the quality of the goods/services (e.g. legal requirements, standards, instructions, rules, internal requirements, information from catalogues, price lists, etc.);
- requirements for the approval of processes, procedures and equipment;
- requirements for personnel qualifications and competencies;
- the deadline and method for supply or service provision;
- commercial terms;
- special requirements (e.g. requirements for the approval of quality and/or procedures of implementation, method of takeover, environmental requirements, marking requirements, requirements for the introduction or presentation of the management system, nuclear and radiation safety requirements, etc.);
- the requirements referred to in Article 67 of JV5 (with due regard to the graded approach) must be incorporated into the criteria.

In order to ensure compliance of the procurement of goods and services with ARAO's requirements, the following activities are carried out:

- supervision of the goods/services supplied or establishment of compliance with the regulatory requirements;
- supervision of suppliers/contractors on the basis of adherence to the requirements for the implementation of procurement orders;
- establishment of non-compliance and changes, and the method of resolution;
- cooperation with suppliers.

During cooperation with suppliers, suppliers' performance is monitored by means of checks to ensure that the agreed requirements of the public contract or the criteria established are being met.

In accordance with the contractual requirements, ARAO may, prior to and during cooperation, verify the effectiveness of external contractors' management system. The possibility of assessment as a means of examining the effectiveness of subcontractors' quality system must be agreed in advance and specified in the relevant contract. The type and frequency of performance of assessments of external contractors depends on the importance of the planned works (graded approach). This is performed in cases where the effectiveness of the

management system is verified in greater detail or the tenderer is checked in terms of its actual capacity to ensure high-quality provision; it can also be performed in cases of thoroughgoing changes to an external contractor's management system.

3.3.12 MEASUREMENTS, ASSESSMENT AND IMPROVEMENTS

In order to ensure the desired results of processes and identify opportunities for improvements, the following are provided in Phase II of the LILW repository project:

- monitoring and measurement of the performance of the management system via the supervisory steering group;
- activities assessed by the heads responsible for them;
- assessment of project management and the management system conducted by an independent organisation;
- the performance of the management system for the LILW repository project, as well as of the management systems of external contractual providers and suppliers, also checked as part of the planned periodic reviews of ARAO's management system;
- identified non-compliances and corrective and preventive actions managed in accordance with Chapter 5 of the PVP II manual [13];
- plans for improvement drawn up, the implementation and completion of which are monitored by the project supervisory steering group;
- an analysis of the entire phase performed at the end of Phase II, and plans for improvement incorporated into Phase III and, where necessary, into subsequent project phases.

On the LILW repository project, the planning results shall be verified in an appropriate form that enables verification in relation to the requirements of the project inputs. Adequate staff shall be in place for the management and implementation of systematic checks to confirm that the objectives and results have been achieved.

Checks and verifications shall be performed at appropriate levels and at selected points of the planning, realisation and project completion process in order to:

- assess the capacity to meet the requirements at the relevant levels of realisation of a product or service;
- identify problems and ensure that the necessary measures are carried out;
- verify the compliance of the product or service with the regulatory (input) requirements.

All records of checks and verifications shall be maintained in the quality file in accordance with the provisions of the record management process.

Requirements shall also be carried, where required, into the repository trial and regular operation phase, in accordance with the applicable ARAO Management Rules of Procedure. For processes, indicators and their target/desired values shall be established/defined for measuring the results of processes and the performance of assessments. Based on the measurement of processes or the performance of assessments, the effectiveness of the implementation of processes shall be assessed transparently and effectively by means of a comparison between the value of the indicator and its defined target value. Any measures

required to improve the effectiveness of processes shall be adopted in response to any deviations in the values of indicators from the target values.

3.3.13 MANAGEMENT OF NON-COMPLIANCE AND CORRECTIVE/PREVENTIVE ACTIONS

All non-compliances in the project shall be analysed so that their root cause can be identified, and the appropriate corrective actions defined and carried out in order to prevent a recurrence.

Products or processes that do not comply with the specified requirements are identified, excluded, controlled, recorded and, after assessment by the project head or the supervisory steering group, reported to the design board and thereby to ARAO management. The impact of the non-compliance is assessed and the non-compliant product or process:

- accepted;
- corrected within a specific timeframe; or
- excluded and rejected or destroyed in order to prevent its inadvertent use.

The schedule for the management of non-compliances and corrective/preventive actions is defined in greater detail as part of the description of the process of managing change in Chapter 5 of the PVP II manual [13]. Requirements shall also be carried, where required, into the repository trial and regular operation phase and implemented in accordance with the applicable ARAO Management Rules of Procedure.

Requirements shall also be carried, where required, into the repository trial and regular operation phase, in accordance with the applicable ARAO Management Rules of Procedure. An electronic information system/database shall be established to collect all notifications of non-compliances, their causes and the measures adopted to eliminate/prevent them; this will facilitate a more transparent and effective analysis of the non-compliances identified in order to prevent them.

3.4 CONCLUSIONS

Radioactive waste must be managed in such a way as to avoid transferring the burden to future generations. We must find safe, cost-effective, usable and environmentally acceptable solutions for the long-term management of radioactive waste. The management system plays an important role in this, and must be established for all phases of radioactive waste management, from generation to safe disposal.

ARAO has in place a management system that covers the aspects of safety, health, the environment, protection, quality and economics [12]. The management system has been aligned with the applicable legislation and the IAEA recommendations. Its compliance with the requirements of the applicable ISO 9001 standards is verified annually by an independent certification body in Slovenia.

ARAO has in place a system of continuous improvement the operation of which enables the provision of safety to human beings as well as the environment; this also applies to the management of the integrated LILW repository project and the management of the entire lifecycle of the repository. Implementation of the results of the continuous improvements enables the strategic objectives to be realised and the safety culture at ARAO to be further developed.

The PVP II manual [13], which has been harmonised with the ARAO Management Rules of Procedure [12], defines the system of planning, management and supervision of the implementation of activities in Phase II in greater detail, i.e. from the completed siting process up to the acquisition of a construction permit. This chapter has outlined the development of the management system, which will be documented in manuals produced for every subsequent phase of the integrated LILW repository project (construction, trial operation and regular operation of the repository).

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