FOURT
NATIONAL REPORT
OF BOSNIA AND HERZEGOVINA

on the implementation of the obligations under the

Joint Convention on the Safety of Spent Fuel and on the Safety of Radioactive Waste Management

To the 8th Review Meeting

State Regulatory Agency for
Radiation and Nuclear Safety

August 2024

CONTENT

Section A: Introduction

Bosnia and Herzegovina deposited an instrument of accession to the Joint Convention (JC) on 02 August 2012. There were no declarations or reservations attached to the instrument of accession. The Convention entered into force for Bosnia and Herzegovina on 31 October 2012.

Bosnia and Herzegovina submitted its first report to the 5th Review meeting in 2015, second report on the 6st review meeting in 2018 and third report on the 7st review meeting in 2020. For the sake of coherency and for presenting a readable overview, much of the text from the previous national report is repeated here. The progress achieved between October 2020 and August 2024 is reflected in this report. The aim of this national report is to demonstrate that Bosnia and Herzegovina seeks to meet its obligations under the JC.

Bosnia and Herzegovina is a non-nuclear country located in Southeastern Europe with a population of approximately 3.4 million people and an area of approximately 50.000 km2. The country is politically decentralized and has two administrative entities and one district. Both entities and a district have their own government. The Council of Ministers acts as the state government.

The Council of Ministers of Bosnia and Herzegovina at August 2018 has passed a decision on the adoption of the Bosnia and Herzegovina Framework Energy Strategy until 2035. In the Energy Strategy till 2035 have not expressed intention of Bosnia and Herzegovina to build nuclear power plants for production electricity on the country's territory. For now, the country has sufficient energy resources, and in our history, this issue has never been on the agenda for the consideration by the relevant authorities. Now country start with decarbonize and installations renewable sources for production electricity (wind and solar).

While Bosnia and Herzegovina does not have any nuclear facilities or isotope production in its territory, it does have radioactive materials (sealed and unsealed) that are used in medical, industry and research activities, and as a result has a number of issues to be solved problem with historical disused sealed radioactive sources (DSRS) which are not use mostly categories 5 and 4. DSRS categories 1, 2, 3, 4 and 5 which use after disused send back to producers DSRS.

The current system of regulatory control of ionizing radiation sources in Bosnia and Herzegovina has been completely reorganized and updated to ensure that radiation and nuclear safety, based on the 2007 Law on radiation and Nuclear safety in Bosnia and Herzegovina, is as much as possible in compliance with IAEA standards and European Union Directives. Regulatory authority for radiation protection and nuclear safety of Bosnia and Herzegovina proper with international support EU Project draft new Law. Plan is publishing new Low in 2025 after adapted Parliamentary assembly of Bosnia and Herzegovina.
An inventory of radiation sources, including sealed radioactive sources of all five categories, exists in Bosnia and Herzegovina and is maintained routinely in RAIS 3.3

software by State Regulatory Agency for Radiation and Nuclear Safety (SRARNS). Now Bosnia and Herzegovina, regulatory authority SRARNS, start with RAIS Plus like member state of IAEA in pilot IAEA Project.

SRARNS is a regulatory authority at the state level and there is no overlapping in its responsibilities with other authorities on any level in Bosnia and Herzegovina, therefore SRARNS regulates radiation protection and nuclear safety and security on the whole territory, as well as all radiation practices in the country.

Currently, in Bosnia and Herzegovina radioactive material (majority in form of disused sealed radioactive source) is stored in two temporary central storage and seven interim storage locations. Majority of these interim storage are located in companies that used radioactive material in their previous and actual activity. We have also eight locations with maximal four disused sources Category 5 (Section L Annex 1). Only one locations is licensed and accept new radioactive sources in case of emergency. As of August 2024, new centralized radioactive waste management facility has identified but not jet permission of Council of ministries of Bosnia and Herzegovina.

Owing to the legacy of the past, the possibility of orphan sources existing in Bosnia and Herzegovina cannot be ignored. The legal and regulatory system provides a firm framework and the responsible organizations have appropriate procedures and equipment for the effective and efficient management of possible situations associated with orphan sources. Also SRARNS plans financial resources in the budget every year to solve emergency situations with orphan radioactive sources.

As a Contracting Party to the Joint Convention, Bosnia and Herzegovina is in the process update laws, policies, strategies and regulations regarding management radioactive waste. The national strategy of radioactive waste management and disused sealed sources (DSRS) has been publish in 2014 by Council of Ministers of Bosnia and Herzegovina. Majority of defined measured (establish new Central radioactive storage) have not yet been implemented. New is prepared draft of update national strategy during EU Project and plan publish in 2025. The regulation on radioactive waste and DSRS management has been published in 2015, in accordance with the national strategy. During EU Project prepared new draft of The regulation on radioactive waste and DSRS management in compliance with EURATOM Directive 70/2011. The new location for establishment of the new Central radioactive waste storage for all DSRS and radioactive waste from Bosnia and Herzegovina has been defined, but is still in the process of approval by the of Council of Ministries of Bosnia and Herzegovina. There is an option of refurbishing and updating existing licensed temporary Central radioactive waste storage Rakovica for all DSRS and radioactive waste from all Bosnia and Herzegovina. Although the disposal of radioactive waste is not defined in the strategy documents. Bosna and Herzegovina have in mind the interim nature of storage and will define possible disposal options in the revision of national strategy of DSRS and radioactive waste management. Possible solution for Bosnia and Herzegovina is bore hold disposal for DSRS Cat 3, 4 and 5.

It is important to emphasize that Bosnia and Herzegovina has ratified most major international instruments (conventions and political commitment of Code of Conduct on the Safety and Security of Radioactive Sources and all associated guides) in the nuclear field and is deeply committed to the implementation of its international obligations.

The main developments since previous national report are:

- Bosnia and Herzegovina hosted the IAEA IRRS mission which was in November and December of 2022.
- Bosnia and Herzegovina have finish EC DG DEVCO (now Directorate-General for International Partnerships) project Support to Regulatory Authority of Bosnia and Herzegovina regarding Radioactive Waste Management which started in February 2020 and finish in July 2024.

In addition, Bosnia and Herzegovina would like to emphasize the importance of the articles: 13, 20 and 27 of the Convention, in relation to plans by the neighboring state Republic of Croatia, presented at the Fifth, Sixth and Seven Review meeting of the JC, to establish a storage facility for radioactive waste LA & IA from NPP Krsko, institutional waste and DSRS from Republic of Croatia along the very border with Bosnia and Herzegovina and nature park Una. Republic of Croatia did not follow article. 13 (iv) of JC when it was defining the location for proposed facility. Local community in Bosnia and Herzegovina, close river Una, is very afraid from intention Republic of Croatia to establish Radioactive waste facility close border of Bosnia and Herzegovina.

Section B: Policies and Practices – Article 32 Paragraph 1

This section's paragraphs on spent fuel management are not applicable to Bosnia and Herzegovina.

Policy on the safety and security of ionizing radiation sources in Bosnia and Herzegovina document was adopted by the Council of Ministers in 2012. This document is compatible with IAEA standards, in particular the IAEA Safety Fundamentals and the Code of Conduct on the Safety and Security of Radioactive Sources, and is based on the main objectives and principles of the safety and security of ionizing radiation sources.

The objective of the Policy is establishment of an efficient and transparent radiation protection system, thus ensuring the basis for protection of the people and the environment against harmful effects of ionizing radiation in accordance with international standards.

In addition to general objectives and main principles, this document contains five specific policies, including radiation safety, nuclear safety, safe management of radioactive waste, safe transport of radioactive material, and security of radioactive and nuclear material.

Main elements of the policy on the safe management of radioactive waste are:

- SRARNS shall establish a regulatory framework, in accordance with international standards, for the safe management of radioactive waste generated in the Bosnia and Herzegovina territory.
- SRARNS authorizes technical services for safe management of radioactive waste. Such authorized services shall be responsible for the implementation of measures and activities regarding the radioactive waste management, including collection, transport, packaging, handling, conditioning, storage, and final disposal of radioactive waste.
- All activities related to the radioactive waste management shall be carried out openly and transparently, and the public shall have access to the information insofar as it does not violate national laws, security and defense.
- The responsibility for radioactive waste shall rest with the authorization holder until the radioactive waste is being taken over by the technical service authorized for radioactive waste management. The authorization holder generating radioactive waste shall be responsible for the implementation of measures with the aim of generating minimal amounts of radioactive waste.
- Sealed radioactive sources of category 1, 2 and 3 shall be imported provided that the importer can ensure they will be returned to the supplier after termination of their use by the authorization holder.
- Radioactive waste shall not be imported in Bosnia and Herzegovina.
- Final disposal of radioactive waste was not elaborated in details, but it is defined that a solution for final disposal shall be sought in future.

The policy on the safe management of radioactive waste foresees the development of a national strategy of radioactive waste management, as well. Strategy is foreseen as a plan for implementation of the policy. National strategy of radioactive waste management was adopted by the Council of Ministers in the end of 2013 and publish in Official Gazette in January 2024. This document complements the policy of safe management of radioactive waste, and defines the following main strategic goals:

- Centralized radioactive waste management facility, owned and financed by the state, for all radioactive waste and disused sealed radioactive sources (DSRS);
- Operator of the centralized facility shall be authorized by SRARNS;
- Radioactive waste generated by previous practices, including DSRS in interim storages and lightning rods with sealed radioactive sources will be collected in the centralized facility for conditioning and long-term storage;
- Generators of radioactive waste will pay fees for radioactive waste storage.

During Project EC former DG DEVCO (now Directorate-General for International Partnerships) Support to Regulatory Authority of Bosnia and Herzegovina regarding Radioactive Waste Management (RWM) which started in February 2020 and finish in July 2024 external expert proposed to be updated Strategy of radioactive management that, not only in terms of the actions needed for its implementation, but also by inserting the missing provisions, such as assigning the ultimate responsibility for RWM in Bosnia and Herzegovina to the state, including all RWM principles, inserting a clear statement regarding the disposal solution(s), clarifying the funding mechanism for RWM, considering the future quantities of RW expected to be generated.

In August 2024 Bosnia and Herzegovina has licensed centralized radioactive waste management facility with operator Public health institute of Federation Bosnia and Herzegovina and two solution for refurbish existing facility or establish new Central storage facility. Currently, radioactive material DSRS is stored on locations around the country, as reported in the Section D and Annex 2.

Classification and categorization of radioactive waste are defined in the regulation on radioactive waste management. Radioactive waste classification system is based on the IAEA scheme (IAEA General Safety Guide GSG-1, 2009) and done according to the activity and half-life. Nuclide specific exemption and clearance levels are laid down in the Regulation on notification and authorization of radiation practices. The categorization of radioactive sources is given in the Regulation on Notification and authorization of ionizing radiation sources, in addition, the categorization of sources according A/D values and security is given in the Regulations on the security of nuclear material and radioactive sources. The categorization of disused sealed radiation sources is the same as for sealed sources in use.

Practices with regard to disused sealed sources are reported in Section J.

Section C: Scope of Application – Article 3

The present report does not refer to the safety of spent fuel management because Bosna and Herzegovina does not have any nuclear facilities, which used fuel, nor have ever had any these facilities, hence there is no spent fuel in the country.

This report applies to the safety of the management of radioactive waste resulting from civilian applications and some from military use in the past, which is now stored in the civilian facilities.

The present report does not apply to waste that contains naturally occurring radioactive material (NORM) exceeding the regulatory clearance levels. NORM material is out of the scope of the regulation on radioactive waste management and will be regulated separately. It is envisaged that the waste containing only naturally occurring radioactivity will be defined as radioactive waste if the exposure to the general public would exceed 1 mSv/a. Draft Regulation that will regulate NORM material in the country should be published in 2025.

Section D: Inventories and Lists – Article 32 Paragraph 2

SRARNS is obliged to maintain a register of radioactive waste including disused sealed radioactive sources existing in the country.

A list of facilities that currently store radioactive material at its premises, as licensing temporary Central radioactive storage end interim storage facility, is given in Annex 1.

An overview of the current inventory is listed in Annex 2.

Section E: Legislative and Regulatory System

Implementing Measures – Article 18

As described below, Bosnia and Herzegovina has taken legislative, regulatory and administrative measures and other necessary steps towards the implementation of obligations under the Joint Convention.

Legislative and Regulatory Framework – Article 19

A system of regulatory control for radiation sources in Bosnia and Herzegovina was originally established within the framework of the Former Yugoslavia more than 60 years ago. Since its declaration of independence in 1992, different organizational structures were in place for the control of radiation sources, but without good results in practice. The Law on Radiation and Nuclear Safety in Bosnia and Herzegovina, published in November of 2007, establishes a basis for the national infrastructure for safety and security of radioactive sources at the state level, and establishes the State Regulatory Agency for Radiation and Nuclear Safety (SRARNS) as the effectively independent regulatory body for radiation protection and nuclear safety and security. This Law establishes the general framework of the system of control over the sources of ionizing radiation, the protection of people, present and future generations, and the environment from exposure or potential exposure to ionizing radiation.
During Project EC former DG DEVCO (now Directorate-General for International Partnerships) Support to Regulatory Authority of Bosnia and Herzegovina regarding Radioactive Waste Management which started in February 2020 and finish in July 2024. Contractor proposed and prepared draft of completely new law which covering all areas of responsibility of SRARNS and including all general requirements that should form the foundation for the secondary legislation. The draft new law is structured in 26 chapters, establishing the scope and the objectives of the law, the safety and security principles, the definitions of the specific terms used in the text to the Regulatory Authority of Bosnia and Herzegovina establishment of SRARNS, its status, funding, functions and responsibilities, the legal basis for the development of national strategies, the general requirements for notification and authorization, for radiation protection, including control of occupational exposure, medical exposure, and public exposure, in planned exposure situations, as well as emergency exposure situations and existing exposure situations, but also the general requirements for RWM, emergency preparedness and response, nuclear security, safeguards, nuclear liability. The title of the law is also proposed to be changed to “Law on the peaceful use of nuclear energy and ionizing radiation”, to reflect the inclusion of non-proliferation and nuclear security requirements. SRARNS have plan start soon with procedure for adopted new Low. Below is content of draft new Low.

Picture 1. Content of draft new Low

The law is compatible with IAEA requirements for safety and security of radiation sources. SRARNS has responsibility for, and is in the process of developing and issuing new regulations in the field of radiation protection and nuclear safety and security, which will regulate this field in details.

The biggest challenge after established SRARNS, and the first task faced by SRARNS at its formation, was the development of legislation in the field of radiation protection and nuclear safety and security and its compliance with the international standards established by the IAEA, as well as with the directives of the European Union. Of particular significance are the legislative provisions that define radiation protection of the population and occupationally exposed persons, and which define radiation protection in medicine, control of radioactive sources of high activity and sources of unknown owners (out of regulatory control), the safe transport of radioactive material, etc. During this period SRARNS drafted regulations governing the process of issuing authorizations for the possession and use of sources of ionizing radiation and for the transport radioactive sources, establishing the grounds for the system that enables the development and use of sources of ionizing radiation in accordance with the requirements for protection of human health and the environment from harmful effects of ionizing radiation.

One of the other primary tasks of the SRARNS was defining policies and principles in the field of radiation and nuclear safety as the basis for its regulatory actions. In this regard, the SRARNS has prepared a draft document entitled "Policy on safety of ionizing radiation in Bosnia and Herzegovina", which the Council of Ministers adopted at the meeting held in June of 2012. This document is compatible with IAEA standards, in particular the IAEA Safety Fundamentals and the Code of Conduct on the Safety and Security of Radioactive Sources. In addition to 2007 Law, this Policy represents the most important document regarding regulatory activity in the country, and covers specific policies, as described in

Section B. The policy on the safe management of radioactive waste foresees the development of a national strategy of radioactive waste management, which is foreseen as a plan for implementation of the policy. The strategy of radioactive waste (including disused sealed sources) was adopted by the Council of Ministers in 2013 and publish in Official Gazette in January 2024. Implementation of this strategy is the highest current priority of all national stakeholders.

Related to international legal instruments, it is important to recognize that Bosnia and Herzegovina is a Contracting Party to the majority of international treaties and conventions in the nuclear field, as listed in Annex 3. In addition, Bosnia and Herzegovina has made a political commitment with regard to the Code of Conduct on the Safety and Security of Radioactive Sources and the Supplementary Guidance on the Import and Export of Radioactive Sources and Joint Convention. In addition, BOH has made a political commitment with regard to the Code of Conduct on the Safety and Security of Radioactive Sources and the Supplementary Guidance on the Import and Export of Radioactive Sources and Guidance on the management of Disused Radioactive Sources.

Pursuant to Article 8 of the Law, SRARNS implements the commitments assumed by Bosnia and Herzegovina under international conventions and bilateral agreements relating to radiation and nuclear safety and the application of safeguards for the purpose of non-proliferation of nuclear weapons.

In addition to the above international instruments relevant for nuclear safety, it should be noted that bilateral cooperation has been established, and it mostly pertains to the countries in the region (Croatia, Serbia, Slovenia, Montenegro, North Macedonia, Albania).

This especially pertains to the border control and illicit trafficking of radiations sources, the exchange of experience during the establishment of the regulatory system and in the education of employees of regulatory agency, which are priority fields for all neighboring countries. The cooperation take place through memorandums of understanding.

SRARNS also cooperates with the United States administration, especially with Department of Energy, National Nuclear Security Administration, Office of Radiological Security, that has implemented several projects related to the security of radioactive sources.

As for cooperation with the IAEA, in accordance with the Law SRARNS is the state partner of the IAEA for all radiation protection and nuclear safety and security matters. In addition to the activities toward the implementation of technical cooperation projects, SRARNS intensively cooperates with the IAEA in other areas of radiation and nuclear safety and security, such as control of sealed radiation sources, import and export control, transport RAM safety and security, nuclear safety and security, safety of radioactive waste management, and nuclear law. Bosnia and Herzegovina belongs to the group of priority countries that are recipients of IAEA assistance programs of technical cooperation, which is characterized through the support in establishing an adequate regulatory framework and improving the work of SRARNS and other relevant institutions in the country in the area of health care, industry, veterinary, agriculture, environmental protection, etc.

Cooperation of SRARNS with the EU institutions takes place mainly through the implementation of former DG DEVCO (now Directorate-General for International Partnerships) projects in Radioactive Waste Management and radiation protection and nuclear safety. There is an ongoing implementation of the project "Support to Regulatory Authority of Bosnia and Herzegovina" (2020-2024) and "Strengthening the Capacity of the Western Balkans for Radiological and Nuclear Emergency Preparedness and Response" (2020-2023).

In order to exercise regulatory control, mainly through authorization and inspection of radiation practices, SRARNS has issued 23 regulations since its establishment.

These regulations are (official gazette number and year of publication is given in the brackets):

1. Regulation on the notification and authorization of practices involving sources of ionizing radiation (Official Gazette of BiH, No 66/10),
2. Regulation on inspection monitoring in the field of radiation and nuclear safety (Official Gazette of BiH, No 65/10),
3. Regulation on the requirements for trade and use of sources of ionizing radiation (Official Gazette of BiH, No 66/10),
4. Regulation on the ionizing radiation protection in medical exposure (Official Gazette of BiH, No 13/11),
5. Regulation on the categorization of radiation threats (Official Gazette of BiH, No 102/11),
6. Regulation on the radiation protection in occupational exposure and public exposure (Official Gazette of BiH, No 102/11),
7. Regulation on the control of high-activity sealed radioactive sources and orphan sources (Official Gazette of BiH, No 62/12),
8. Regulation on record keeping for legal persons carrying out practices involving sources of ionizing radiation (Official Gazette of BiH, No 67/12),
9. Regulation on the safety of transport of radioactive material (Official Gazette of BiH, No 96/12),
10. Regulation on the security of nuclear material and radioactive sources (Official Gazette of BiH, No 85/13),
11. Regulation on recognition of the qualified expert status (Official Gazette of BiH, No 84/14),
12. Regulation on the monitoring of radioactivity in the environment (Official Gazette of BiH, No 54/14),
13. Regulation on the concentration limits for radionuclides in food, feed, medicines, items of general use, building materials, and other goods placed on the market (Official Gazette of BiH, No 54/14),
14. Regulation on the training in ionizing radiation protection (Official Gazette of BiH, No 68/15),
15. Regulation on radioactive waste management (Official Gazette of BiH, No 68/15),
16. Regulation on the medical surveillance of occupationally exposed workers (Official Gazette of BiH, No 68/15),
17. Regulation on technical services for ionizing radiation protection (Official Gazette of BiH, No 68/15),

18. Regulation on the radiation protection officer (Official Gazette of BiH, No 86/15)
19. Regulation on the national register of individuals exposed to ionizing radiation (Official Gazette of BiH, No 86/15),
20. Regulation on the radiation protection of outside workers (Official Gazette of BiH, No 86/15),
21. Regulation on the radiation protection and medical physics service (Official Gazette of BiH, No 86/15),
22. Regulation on radiological emergency events in practices involving radioactive sources (Official Gazette BiH, No 30/16),
23. Regulation on conditions and method of sealing the premises and devices of end-users by inspectors (Official Gazette BiH, No 83/16).

With the promulgation of 2007 law and implementing regulations, Bosnia and Herzegovina has a legal and regulatory basis that, inter alia, addresses:

- categorization of sources and practices,
- establishment and maintenance of registers of radiation sources,
- requirement for prior authorization to take account of the potential risk,
- requirement for the regulatory body to investigate allegations as related to radiation safety and security of radioactive sources,
- involvement of the public in the regulatory process,
- import and export of radioactive material,
- the processes of exclusion and exemption,
- procedures of review and appeal against regulatory decisions,
- process for removal of a facility or activity from regulatory control,
- implementation of obligations under international treaties, conventions or agreements.

In order to strengthen regulatory control and facilitate the implementation of regulations and regulatory requirements by end users, SRARNS prepared and published on its web site several guidance documents:

1. Guide for the classification of controlled and supervised areas and the categorization of occupationally exposed workers, students, and persons in training,
2. Guide for the preparation of the radiation protection program in diagnostic radiology,
3. Guide for the radiation protection of occupationally exposed workers, pregnant and breastfeeding women,
4. Guide for radiation protection of pregnant and breastfeeding patients in medical exposure,
5. Guide for handling discovered orphan sources,
6. Guide for the recognition of the qualified expert status,
7. Guide on radiation safety procedure for technical services,
8. Guide on the contents of radiation protection training for radiation protection officers,
9. Guide for use of personal dosimeters

The process of notification and authorization is regulated by the regulation on notification and authorization of practices. As a result, SRARNS is able to issue licenses for the following activities:

- the possession and use of sources of ionizing radiation;
- transportation of radioactive sources;
- import and export of radioactive sources;
- technical services (operator of RAW management facility);
- procurement and distribution of sources of ionizing radiation;
- production of radiation sources.

In accordance with the 2007 law and regulations on internal organization and job classification, the SRARNS encompasses the inspectorate, which performs work under its jurisdiction, through the inspectors in the SRARNS headquarters and regional offices. State inspectors carry out control of radiation and nuclear safety. The field of work and special authorities of inspectors are defined by the2007 law, administration law and the regulation on inspection in the field of radiation and nuclear safety. All persons who possess or use radiation sources, or are engaged with radiation sources, are subject to regulatory inspection. Authorized technical services are also subject to inspection by SRARNS, in order to guarantee the conditions under which they are authorized, as well as the accuracy of their work.

Establishing and maintaining a comprehensive inventory of radiation sources is one of the key factors for a successful regulatory system in every country. Therefore, pursuant to an article of the law which defines the functions and responsibilities of the SRARNS, among other things stipulated is to establish and maintain the state register of radiation sources and persons exposed to ionizing radiation, as well as a register of issued authorizations. This important activity is carried out through the collection and processing of information and data in the information management system tool RAIS (IAEA's Regulatory Authority Information System), which was established with the support of the IAEA. SRARNS is currently using the web version RAIS 3.3 and start with pilot project RAIS Plus, web that is adapted for the SRARNS needs, and provides an acceptable database for all their regulatory activities, including the state register of radiation sources, both in use and spent/disused.

Through a combination of accurate and detailed records of radiation sources from the past, a process of notification and authorization, and extensive on-field work of SRARNS inspectorate, the state register is up-to-date for all five categories of sealed radioactive sources in use and also for radiation generators. The register maintained by SRARNS, contains data on issued authorizations and occupationally exposed workers, too. RAIS has proven to be a very useful tool for instance in the planning of inspections. All radioactive sources that are not in use have to be notified to SRARNS, but there is no authorization process for these sources, only regular inspections by SRARNS inspectorate are performed. Inventory of DSRS in the country exists and is maintained by SRARNS, although it is not always completely verified by SRARNS. DSRS inventory relies on declarations by end-users and verification by SRARNS inspectorate where it is possible.

Regulatory Body – Article 20

State Regulatory Agency for Radiation and Nuclear Safety (SRARNS) - Regulatory body was formed by the Law on Radiation and Nuclear Safety (2007). SRARNS, independently and in accordance with the law and other regulations, performs regulatory control of radiation protection and nuclear safety and security, including safety of radioactive waste and safety and security of the transport. SRARNS is also in charge of the implementation of safeguards agreements in Bosnia and Herzegovina.

SRARNS has the authority to (Article 8 of the 2007 law):

- define policy in the field of radiation and nuclear safety, security principles and relevant criteria as the basis for its regulatory actions;
- prepare and issues regulations and guidelines on which its regulatory actions are based;
- define the radiation exposures that are excluded from the framework of the regulations on the basis that they are not subject to regulatory control;
- establish and implement procedures for notification, authorization, inspection and enforcing regulatory requirements;
- require that each operator implements a safety assessment;
- enters, at any time, in the space or facility to perform state safety inspection of radiation sources;
- issue, supplement, suspend or take away and sets the terms of authorization for the import, export, manufacture, purchase, receipt, possession, storage, use, transit, transportation, maintenance, recycling and final disposal, as well as any other activity in connection with sources of ionizing radiation;
- issue, supplement, suspend or withdraw licenses from technical services for radiation protection;
- determine exclusions and exemptions relating to the possession and use of radiation sources and issues relevant document;
- take appropriate measures in case of radiological emergency events and nuclear accidents;
- establish and maintain the State Register of sources of ionizing radiation and persons exposed to ionizing radiation, as well as licenses issued;
- cooperate with other authorities and other institutions in relation to the content of work of SRARNS;
- establish appropriate methods of dissemination of public information on matters of ionizing radiation;
- determine the proposed amount of fees (taxes) for the issuance of authorization or approval, and to handle the collection of the fee;
- cooperate with other countries, the International Atomic Energy Agency (IAEA) and other relevant international organizations;
- to be a state partner of the International Atomic Energy Agency (IAEA);
- represent Bosnia and Herzegovina at the international level on issues in the field of radiation and nuclear safety;

– take the necessary measures for the safety of radioactive and nuclear materials, in collaboration with relevant government agencies, and to seek, from other relevant authorities to carry out the monitoring within the state and at the necessary control points in order to detect sources that are not under regulatory control;
– be prepared to assist in emergency situations and react in accordance with the national action plan for emergency situations;
– establish formal arrangements with other relevant agencies involved in the regulatory process;
– provide opinions and recommendations to join the international conventions, as well as recommendations for the adoption of other international documents in the field of radiation and nuclear safety;
– carry out obligations which Bosnia and Herzegovina has assumed under international conventions and bilateral agreements relating to the Radiation and Nuclear Safety and the application of safeguards to nuclear nonproliferation.

The SRARNS' headquarters is in Sarajevo, the capital of Bosnia and Herzegovina. SRARNS, according to 2007 law, established two regional offices in Banja Luka and Mostar. The headquarters has four organizational units as follows:

– Office of the Director;
– Department for general, legal, personnel and financial affairs;
– Department for authorization;
– Inspectorate.

Rulebook on internal organization and job classification defines that SRARNS employs a total of 34 employees. Today it operates with 18 and 1/2 employees, which amounts to 54% of the estimated number of employees by classification. In addition to employees, a significant support to the SRARNS work gave engaged outside experts during EU and IAEA Project, who participated in the drafting of regulations and other documents adopted or proposed by SRARNS.

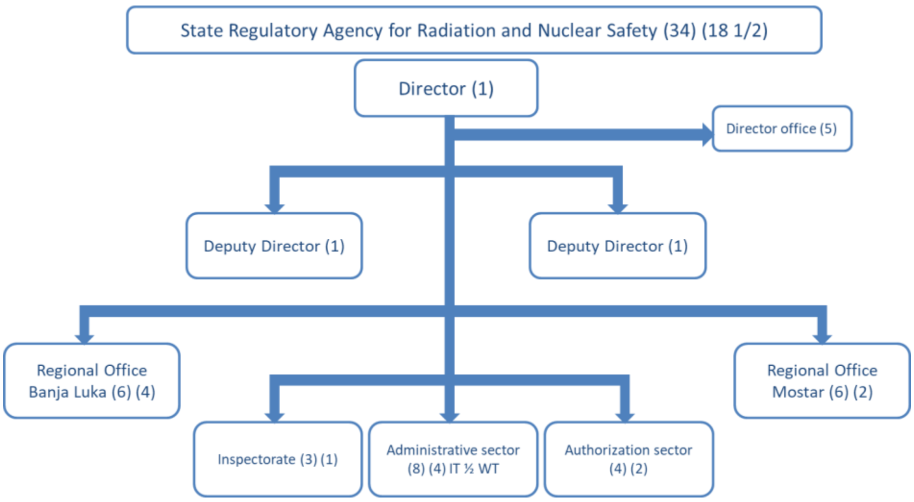

Figure 2 : SRARNS organizational structure in brief with the numbers of planned and filled positions

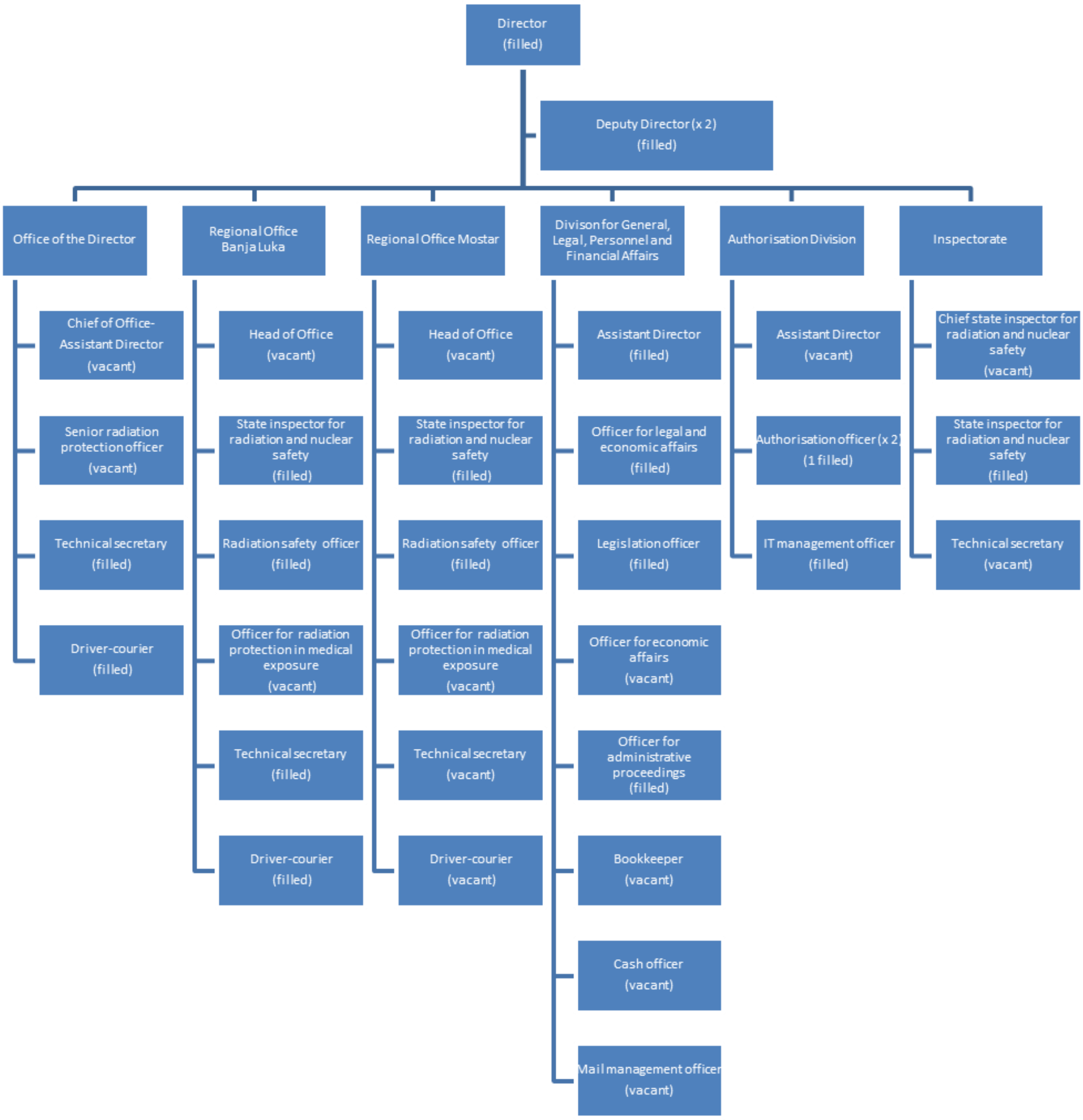

Figure 3: SRARNS organizational chart

SRARNS is an independent administrative organization that executes its powers under the direct supervision of the Council of Ministers of Bosnia and Herzegovina. It is independent of other governmental and non-governmental organizations involved in the promotion of radiation technology. SRARNS is completely funded by the budget of the institutions of Bosnia and Herzegovina, and from independent sources. Funding is not dependent on collected taxes for authorization or inspection penalties.

SRARNS annually reports on its activities to the Council of Ministers of Bosnia and Herzegovina. It carries out the activities provided for in the annual plan of the Council of Ministers, too.

In addition, the Report on radiation and nuclear safety in Bosnia and Herzegovina has to be delivered to the Parliamentary Assembly of Bosnia and Herzegovina at least once a year.

Section F: Other General Safety Provisions

Responsibility of the license holder – Article 21

Under the Law on Radiation and Nuclear Safety in Bosnia and Herzegovina, primary responsibility for the safety of radiation sources shall be borne by the authorization holder, i.e. licensee and registrant (Article 15 of the law 2007).

Authorization holders are fully responsible in respect of all regulatory provisions concerning the safe management of their radioactive material. They have to ensure the safe management after use of radioactive material, as well as the implementation of radiation protection measures.
If we follow article 5. of Regulation on radioactive waste management (Responsibilities for waste management)

(1) The responsibility for radioactive waste management rests with:

a) The radioactive waste generator has the prime responsibility for the waste generated during its authorized practice, including the financial liability for further steps in waste management;
b) The storage facility operator, for the waste accepted in the facility and the waste generated during the waste management operations in the facility;
c) The SRARNS has the ultimate responsibility for the safe management of the waste generated by unknown subjects, including the financial liability for the waste.

(2) The responsibility for the waste management may not be transferred to other legal persons, except in the cases and as provided for in the law and approved by the SRARNS.

Human and financial resources – Article 22

Human and financial resources of the regulatory body – SRARNS are described in Section E – Regulatory body.

Users of radioactive material are constrained by legislation to provide adequate human resources to guarantee the safety of their radioactive sources and waste. All the licensees have to nominate a qualified radiation protection officer who is responsible to implement the obligations of the license and the radiation protection measures in its facility. The radiation protection officer has to be recognized by SRARNS in line with the Regulation on radiation protection officer.

In the area of radioactive waste management Bosnia and Herzegovina have only one Radioactive waste management expert recognize by SRARNS in line with Regulation on recognized expert. Also in Bosnia and Herzegovina have some trained personnel exist, but only several persons are trained in conditioning of radioactive sources of category 4 and 5. Currently, this number is insufficient for any conditioning campaign on a higher scale.

Quality assurance – Article 23

Regulatory authority SRARNS has Management manual. Management policy (or quality policy) in the SRARNS is based on its mission, vision and values. It also includes the understanding of what SRARNS customers and the broad society need, expect and demand. The policy is in line with the quality policy of public administration in the state-level institutions.
The management system takes into account all relevant legislation and the requirements of the International Atomic Energy Agency standard Leadership and Management for Safety (2016).
The management commits itself to continuously follow SRARNS vision, management policy and strategic objectives.

The management is also aware that strict adherence to the values and ethical principles set out in the 'Code of conduct for civil servants' (in the state-level institutions) and the codes of ethics for civil servants at the lower government levels contributes to ensuring a high level of radiation and nuclear safety.

The management follows the management policy by implementing measures and setting own personal examples, encouraging employees to follow the examples, thus contributing to the constant improvements in the management system and successful SRARNS operations. The adequacy of the management policy is constantly monitored.

The management ensures that the vision, mission, values and the management policy are communicated to the employees, understood and implemented at all SRARNS levels.

SRARNS implements the management policy by developed and constantly improving procedures, encouraging and recognizing creativity, motivating all personnel and promoting positive attitudes. Through their work, the employees fulfil the management system requirements that affect safety, health, environment, security, quality, economy and as well as the satisfaction of customers, employees themselves and other stakeholders. SRARNS employees are aware that ensuring safety is an overriding requirement in the implementation of all activities.

The radioactive waste generator and the operator must establish an appropriate management system in order to ensure the required level of quality commensurate with the risk of waste management.
The management system referred to the waste generator and waste operator must contain:

a) Operational policy and procedures defining radiation safety as a priority in waste management;
b) Organizational structure with defined powers and responsibilities of all persons involved in the waste management process;
c) The measures for identifying and solving problems commensurate with their influence on the waste management activities;
d) Provisions about relevant qualifications and training of the persons involved in the waste management process;
e) Provisions to ensure data confidentiality for all legal persons involved in the waste management process;
f) A quality assurance program demonstrating the fulfillment of requirements for the safe management of waste.

SRARNS processes are shown in Figure 4.

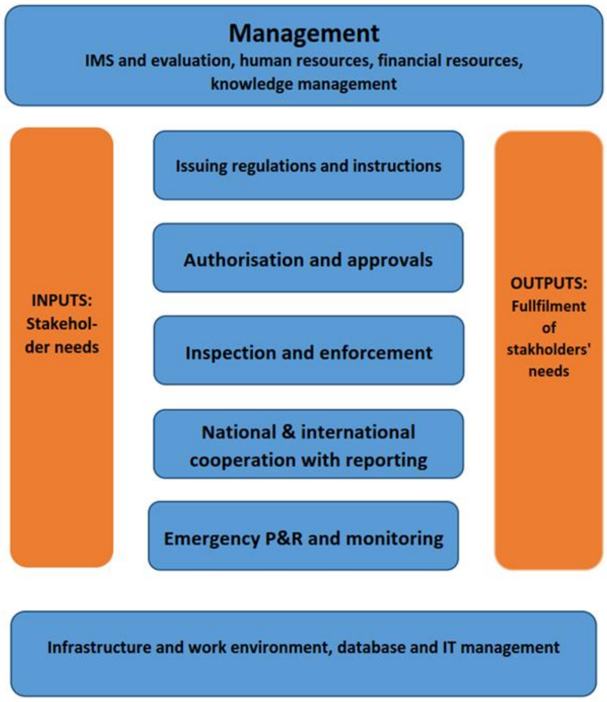

Figure 4: SRARNS processes

SRARNS will prepare an organizational procedure (OP) for each process/sub process. The owner of each process is responsible for reviewing the prepared OP relating to the process. The OP will be periodically reviewed by its owner/author. The employees who will use a certain OP and new employees will be informed about the OP content by its author/owner.

SRARNS will prepare detailed organizational instructions (OI) for each relevant task in the process/sub process. The owner of each process is responsible for reviewing the prepared OI relating to the process. The OI will be periodically reviewed by its owner/author. The employees who will use a certain OI and new employees will be informed about the OI content by its author/owner.

The processes need to cover:

- -Radiation safety (including radiation protection),
- -Nuclear safety,
- -Transport of radioactive material,
- -Security,
- -Environmental monitoring and
- -Safeguards.

Each employee in the field of their expertise and the personnel as a whole implement and improve the SRARNS system of work. Each employee is responsible for carrying out their duties in a quality and timely manner.

Quality assurance programs are requested from end-users on a regulatory base in the field of operational radiation protection and quality control of equipment and procedures, and are subject to the regulatory inspection of a facility by SRARNS.

Operational radiation protection – Article 24

Regulation on the radiation protection in occupational exposure and public exposure lays down the operational radiation protection requirements for authorization holders. The objective of this regulation is to establish standards and criteria for the radiation protection of exposed workers and the population. It prescribes, inter alia, the principles of radiation protection of exposed workers and the population in ordinary situations, radiological and nuclear emergencies; principles of the radiation protection system; dose limits for exposed workers, apprentices, high-school and university students in training, and the population; responsibilities of the radiation protection experts.

Radiation protection principles include:

- The principles of operational protection: justification, optimization and dose limit;
- Values of dose constraints and dose limits;
- Specific requirements: protection during pregnancy and breastfeeding;
- Radiation safety assessment;
- Protection of exposed workers: prevention of exposure (classification of workplaces), classification of exposed workers into categories, implementation of control measures and assessment of exposure, including workplace monitoring, individual monitoring and medical surveillance.

Implementation of the radiation protection measures by an authorization holder is described in its radiation protection program, which is assessed during the authorization process, and inspected as part of regular regulatory inspection by SRARNS.
During Project EC DG DEVCO (now Directorate-General for International Partnerships) Support to Regulatory Authority of Bosnia and Herzegovina regarding Radioactive Waste Management, contractor proposed revision of the Regulation on Radiation Protection in Occupational Exposure and Public Exposure includes updated provisions, in line with the current EURATOM BSS Directive and the international BSS IAEA GSR Part 3. A new title and a new structure are proposed for the regulation, addressing the different categories of exposure for each type of exposure situation. The scope of the regulation is proposed to be extended in order to cover emergency exposure and existing exposure situations too. Also, the principles of radiation protection are extended to all types of exposure situations. The equivalent dose limits for apprentices and students and for outside workers are introduced, the equivalent dose limit for the lens of the eye is corrected, and the values of the dose constraints are replaced with provisions for establishing dose constraints corresponding to the EURATOM BSS Directive requirements. Also, the investigation levels and registrations levels are replaced with the reference levels established in the BSS Directive EURATOM 59/2013.

Emergency preparedness – Article 25

Bosnia and Herzegovina’s legislation requires local (on-site) emergency plans for all facilities dealing with radiation sources. The radioactive waste generator and the operator must prepare an emergency plan for the management of radioactive waste under their responsibility. Local emergency plan is prepared by the facility, according to its practice and risk, and presented to SRARNS during the authorization process.

The Parliamentary Assembly of Bosnia and Herzegovina adopted the National Emergency Preparedness and Response Plan in 2015. The aim of the plan is establishment of an efficient and successful system of preparedness and response of the institutions in Bosnia and Herzegovina at all levels in case of a nuclear or radiological emergency on the country territory.

The plan consists of four chapters:

- Introduction,
- Response planning,
- Response to a radiation emergency,
- Preparedness for a radiation emergency.

The plan particularly emphasizes an adequate involvement of the institutional capacities and identifies deficiencies in order to work towards their future elimination, which would allow for the establishment of an effective system of public and environmental protection in the event of a radiation emergency.

The plan has defined the powers and responsibilities of institutions in Bosnia and Herzegovina, which will be an opportunity for their active participation in the exercises related to the provision of information, engaging and seeking assistance, regularly organized by the IAEA in cooperation with the Member States.

It is important to emphasize that Bosnia and Herzegovina has an automated on-line system for monitoring environmental radiation and for early warning of a radiation emergency by measuring the ambient dose rate of gamma radiation and identified radionuclide during 2 spectrometry measuring stations. IAEA's support through a national TC project BOH9007 titled Enhancing Radiation Emergency Preparedness and Response Capabilities Bosnia and Herzegovina with new 11 measuring Gamma stations and new server and software DataExpert. In 2023 update automated on-line system for monitoring environmental radiation and for early warning of Bosnia and Herzegovina during EU project with additional 12 Gamma measuring stations and 2 Spectrometry measuring stations which mostly installed on whole territory of Bosnia and Herzegovina and join with EURDEP. Bosnia and Herzegovina ratified International contract EURDEP between EC and Bosnia and Herzegovina. Also in February 2020 is started implementation of EC DG DEVCO (now Directorate-General for International Partnerships) project "Strengthening the Capacity of the Western Balkans for Radiological and Nuclear Emergency Preparedness and Response" (2020-2023) in which Bosnia and Herzegovina will be install J-RODOS.

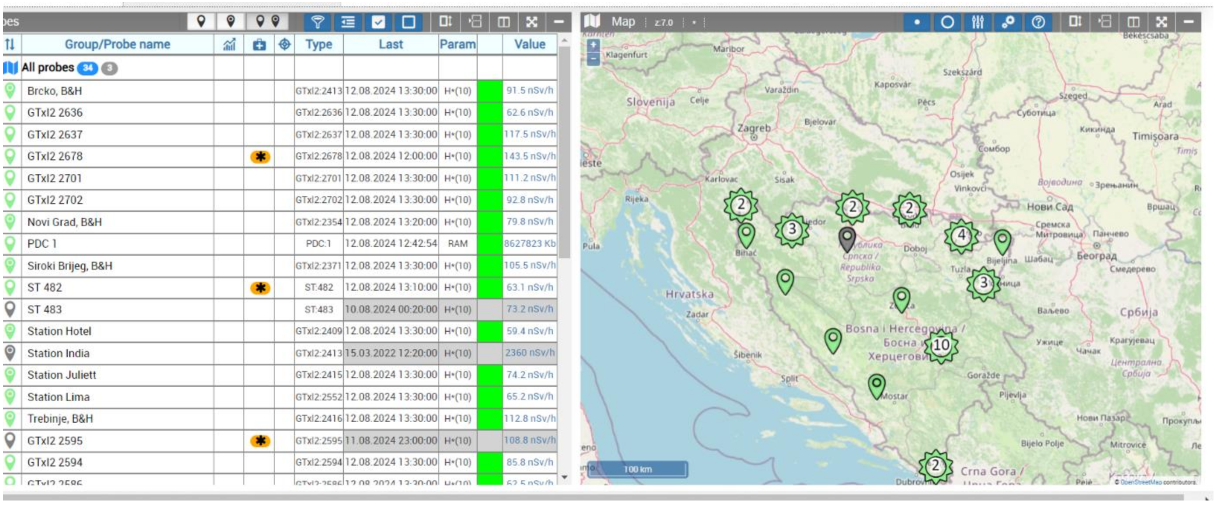

Figure 5: Bosnia and Herzegovina automated on-line system for monitoring

Bosnia and Herzegovina has appointed contact persons for the IAEA USIE (Unified System for Information Exchange in Incidents and Emergencies) platform, and regularly participates in exercises organized by the IAEA in relation to the platform.

Regarding RAW Regulations and Emergency preparedness:

The radioactive waste generator and the operator must prepare an emergency plan for the management of radioactive waste under their responsibility.

As a minimum, the emergency plan must contain:

a) A description of a potential emergency;

b) Identification of critical conditions during the waste management that could cause an emergency and the need for intervention;

c) A description of methods and activities for emergency assessment and remediation of emergency consequences;

d) The way of informing the SRARNS and other relevant institutions for the purpose of possible initiating an intervention and assistance (medical, firefighting, etc.);

e) A deadline for revision of the plan.

The emergency plan referred to waste generator and the operator must comply with applicable regulations.

Decommissioning – Article 26

Decommissioning of radioactive waste management facilities is stipulated in the Regulation on radioactive waste management.

The operator must prepare a decommissioning plan for the waste storage facility, demonstrating that the planned decommissioning is in line with the radiation safety requirements under the provisions of this regulation and applicable regulations.

The storage facility is decommissioned with a prior approval of the Agency that verifies the completion of the decommissioning process.

As a minimum, the decommissioning plan must contain:

a) A description of buildings within the storage facility;

b) A description of decommissioning process;

c) A description of waste management;

d) A description of costs;

e) A safety assessment of the storage facility during decommissioning;

f) An environmental impact assessment;

g) A description of the final inspection procedure and verification of the decommissioning.

The decommissioning plan must be revised every five years.

The SRARNS provided the IAEA information regarding the radiological contamination incident at Energoinvest industrial radiography Company a site located in Tvornička 3, Sarajevo. That in December 2019, a radiological incident occurred in Sarajevo when a factory hall of about 400 m2 was contaminated with a Cs-137 radioactive source and contamination event occurred. The authorities ordered that the site contaminated with radioactive material Cs-137 be marked as a hazard and public access to the site be prevented on a 24-hour basis. The responsible authorities reported that no increased radioactivity outside the marked site have been detected. As a result, the authorities assess that there is no health risk for the public outside the site. Decontamination work at the site by licensed companies “Nuclear Facility of Serbia” is finish in 2021.

Figure 6: ISO container with VLL RAW after decontamination

Section G: Safety of Spent fuel Management

This section containing articles 4 - 10 is not applicable to Bosnia and Herzegovina.

Section H: Safety of Radioactive Waste Management

General safety requirements – Article 11

The legal regime currently in place (see Section E) and particularly the system of notification, licensing and inspection by the regulatory body is a guarantee for the safe management of a small quantities of waste produced in the country, especially for minimization of the production of radioactive waste. All practices where radioactive materials are used have to be authorized under the radiation safety legislation. Small amounts of short-lived radioactive waste, produced in nuclear medicine departments or research activities, are kept until their activity is low enough to be disposed of as normal waste. The end users are responsible for that all those who handle waste must do it according to accepted written procedures, based on relevant radiation protection regulations and international standards.

The Regulation on radioactive waste management defines general safety requirements for radioactive waste management in the country. It provides for the mandatory measures in radioactive waste management; the responsibility for the waste management; the way of classification, processing, storage, and keeping records of radioactive waste; the way of discharging radioactive waste substances into the environment, and also other important matters related to the waste management.

The regulation applies to the management of radioactive waste:

a) generated through an authorized practice;
b) generated when the authorization has expired, when there is no authorization or when the authorized practice has been terminated;
c) in the form of disused sealed radiation sources declared as waste;
d) generated during an emergency;
e) in other cases in which radioactive waste is generated, including the residues generated in work activities.

According to the regulation, the following mandatory measures should be taken in radioactive waste management:

a) Ensuring the prescribed level of health protection of exposed workers and the public, and the environmental protection;
b) Planning an equal level of health protection of the future generations to avoid imposing any undue burden on them in respect of the waste;
c) Taking into account the possible effects on human health and the environment beyond national borders;

d) The application of graded approach in the safe management of waste in accordance with a waste classification;
e) Using passive means in the safe management of waste;
f) Generating reasonably practicable minimal amounts of waste both in terms of activity and volume;
g) Ensuring appropriate safety and security in waste management;
h) Complying with the principle of interdependency between individual steps in waste management;
i) Keeping accurate records on the activities associated with all stages of waste management;
j) Providing information to the public and adequate participation of the interested public in individual stages of waste management.
Bosnia and Herzegovina received EC support (DG DEVCO, now Directorate-General for International Partnerships) through the project Support to Regulatory Authority of Bosnia and Herzegovina, which finished in July 2024. During the implementation of the Project Bosnia and Herzegovina was supported by/in licensing process of radioactive waste storage facilities (RWSFs) by transferring the best EU practices and in updating the corresponding regulatory framework as necessary to align with the EU Acquis. Also, support was provided with three options which as follows:

a) establishment of a new central radioactive waste storage(s) facility(ies) at a selected location;
b) perform an upgrade of the existing temporary RAW storage facility (in Rakovica) to serve as the central RWSF;
c) perform an assessment of cost of exporting all DSRS. Cost estimates shall be included for all options.

In this moment Bosnia and Herzegovina have Regulations regarding radioactive waste management compliance with EURATOM Directive 70/2011 in 42%. Project proposed new draft Regulations and plan will be publishing in 2025.

Existing facilities and past practices – Article 12

There are several radioactive waste (RAW) storage facilities at those premises where the sources were used and two centralised storage facilities. A RAW storage facility situated in Rakovica near Sarajevo is operated by the Radiation protection centre of Public Health Institute (PHI) of Federation Bosnia and Herzegovina (PHI FBIH), and was used as a centralised storage for the Federation Bosnia and Herzegovina entity and licensed at 14.12.2022 till 14.12.2024. During licencing SRARNS follow Standard working procedure for evaluation of the Safety case. The PHI of Federation of Bosnia and Herzegovina employs some staff members with sufficient knowledge and experience and one RAW expert. PHI of Federation Bosnia and Herzegovina has some equipment for RAW management, but it is still in need of training.

BOSNA I HERCEGOVINA
Državna regulatorna/regulativna agencija za radijacijsku i nuklearnu sigurnost

БОСНА И ХЕРЦЕГОВИНА
Државна регулаторна агенција за радијациону и нуклеарну безбједност

State Regulatory Agency for Radiation and Nuclear Safety

Registracija broj: 4-211-301/21

Na osnovu člana 8. stav (1) tačka h) Zakona o radijacijskoj i nuklearnoj sigurnosti u Bosni i Hercegovini („Službeni glasnik BiH" broj 88/07) i člana 3. stav (1) Pravilnika o tehničkim servisima za zaštitu od jonizirajućeg zračenja („Službeni glasnik BiH" broj 68/15), izdaje se

LICENCA

Zavod za javno zdravstvo Federacije Bosne i Hercegovine

za obavljanje djelatnosti tehničkog servisa za zaštitu od jonizirajućeg zračenja:

Operator privremenog centralnog skladišta istrošenih radioaktivnih izvora/radioaktivnog otpada

Datum prestanka važenja: 14.12.2024. godina

Sarajevo, 14.12.2022. godina

M.P.

DIREKTOR
Marinko Zeljko

Standard working procedure

for

Evaluations of the Safety case

No.	
Applicant	
Name and Surname of the commission member	
Working place	
Name of the evaluated piece of the Safety Case	

Figure 7: Licence Operator of RAWM of PHI and Standard working procedure for SC

Figure 8: Temporary licenced RAWM facility Rakovica

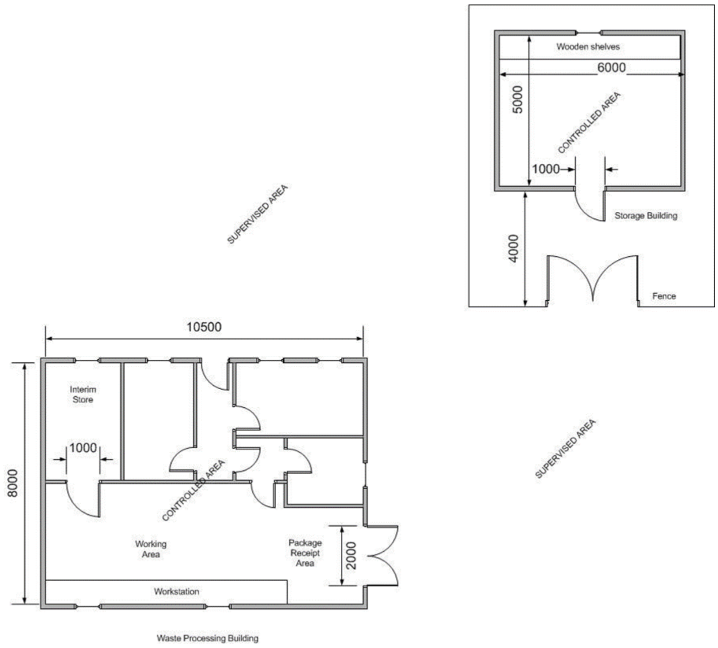

Figure 9: RWSF layout

The other centralised storage facility, for entity Republika Srpska, was in Banja Luka and was operated by the Company Cajavec - MDU Banja Luka. The the Company Cajavec - MDU Banja Luka went bankrupt and all radioactive sources were left in the storage room. Currently this room is under supervision of Institute for Metrology of Bosnia and Herzegovina that operates an SSDL laboratory on the same premises. The Institute for Metrology neither owns the sources nor has the responsibility for them. This problem was left for SRARNS to be dealt with. The majority of the other storage facilities, mainly at industrial sites, are in bad shape and disused radioactive sources are left in their original working containers.

None of the existing storage facilities in Bosnia and Herzegovina is licensed by SRARNS. nor they accept new sources. Public Health Institute (PHI) of Federation Bosnia and Herzegovina finish Safety Case for RAW facility Rakovica before licensed. For the moment Bosnia and Herzegovina has action plan for revised its RAW strategy.

The existing facilities for storage of disused sealed radioactive sources were not separately licensed for the activity of interim storage. A brief safety assessment of those facilities have been conducted in the past, but new regulation will stipulate a comprehensive safety assessment and development of the safety case for all the existing facilities that will continue to serve as a radioactive waste management facility. This requirement should result in the improvement of an overall safety of the facilities (see Section J).

Siting of proposed facilities – Article 13

Siting Criteria for the Central storage facility of RAW in Bosnia and Herzegovina

There are three groups of criteria considered for selection of the potential new site for RAW storage facility:

(1) exclusion criteria – for segregation of unfavorable areas of territory

(2) avoidance criteria – for eliminating feasible but less favorable areas

(3) comparison criteria – for the assessment of selected potential areas/sites in order to select the best site

At the first step in the site selection process unfavorable sites should be excluded from the scope of further investigation. Following that, less favorable sites should be screened out. Finally, the best site should be selected through assessment utilizing comparison criteria.

Exclusion criteria

The exclusion criteria to be met by the potential new site for the RAW central storage facility in BiH are proposed as follows:

- No military airports within 15 km radius of the site
- Probability of aircraft accidents resulting in radiological consequences greater than exposure limits established in Bosna and Herzegovina regulations is less than 10-7 per year. Hence, the following criteria should be satisfied:

  -distance D from the edge of take-off line to the facility is more than 5 statutory miles and the projected annual number of operations is less than 500xD2 or D is greater than 10 statutory miles, and the projected annual number of operations is less than 1000xD2,

  -distance to the nearest edge of airway, holding pattern, or approach pattern not less than 3.2 km,

  -distance to the nearest edge of military training routes not less than 8 km,

  -distance from small airfields not less than 5 km.
- Distance to a military training sites and facilities storing ammunitions not less than 10 km
- Distance to the surface water courses (rivers, permanent or seasonal creeks etc.) not less than 1 km
- No underground cavities (both natural and those deriving from human activities) and potential collapse (e.g. karstic areas in limestone, salt, or other soluble formations) areas
- Very low to low level of natural multi-hazard risk (earthquake, landslide, flood, mudflows and fire hazards combination considered), where:

  -distance to epicenter of know earthquakes greater M=4.0, with return period than 1 per 50 years or less, not less than 5 km,

-distance to any existing or nominated active fault not less than 20 km,

-probability of flooding not higher the 1 per 1000 years

- No terrains prone to rockslides
- No potential unstable slope areas
- No erosion caused by the lithological composition or dynamic relief
- No areas characterized by unfavorable subsoil conditions (liquefaction, surface collapse, subsidence or uplift)
- No protected drinking water sources within 500 m radius
- No forest lands
- Cumulative population density within 5 km radius not greater 80 inhabitants per km2, no residents within 400 m from the site border and distance to nearest residential center with total number of residents exceeding 10000 people not less than 5 km

Avoidance criteria

- Plain ground less than 50m x 100m within the site
- Distance to connection point of electricity distribution network, enabling a minimum of 20 kW load, more than 400 m
- No paved (asphalted) road to the site border ensuring connection with national network of roads
- No sustainable coverage by mobile networks signal
- Distance to nearest base of authorized security service (police station) more than 5 km
- Distance to industrial zones/facilities for manufacture, storage and transshipment of toxic / inflammable / explosive / corrosive chemicals etc. less than 1 km
- Distance to transportation routes (automobile and railway roads and pipelines) of and large-scale storage facilities for liquefied gas and/or oil products less than 1 km
- Distance to borders of national parks, nature reserves and other protected zones less than 1 km
- Distance to coastal line of Adriatic Sea or water reservoirs/lakes less than 2 km
- Distance to the site of any existing and prospective exploration of natural resources e.g. ores, minerals, gas, coal etc. and mining activities less than 2 km
- Less than two evacuation routes from site
- No forest lands sanctuaries within 2 km radius

- No areas characterized by atmospheric inversion
- No areas prone to cyclones, hurricanes
- No areas with shallow ground water table

Comparison criteria

- Away from International border
- Low erosion caused by wind and precipitation
- Minimal variation in temperature (both daily and seasonal)
- Minimal precipitation
- Maximal evapotranspiration
- Minimal current and projected population in the preferential wind direction
- Maximal distance to large and densely populated centers
- Minimal cultivation of lands within 2 km radius
- Preference to areas with rock foundation
- Preference to deeper ground water table
- Minimal irrigation around site
- Easily accessible by road
- Maximal distance to hospitals, schools, agricultural lands, historic, cultural and archaeological sites, commercially exploitable mineral resources, transportation and utility corridors; and recreational areas
- Maximal distance to industrial zones/facilities which could represent risk of impact to the storage system with radiological consequences

Communication plan for introducing radioactive waste management system in Bosnia and Herzegovina

The purpose of the Law on radiation and nuclear safety in Bosnia and Herzegovina is to ensure the protection against ionizing radiation – radiation and nuclear safety of the citizens of Bosnia and Herzegovina.

Therefore, the SRARNS has prepared various activities for introducing radioactive waste management system in Bosnia and Herzegovina according to the new international standards with the focus on abovementioned issues. With these activities SRARNS plans to raise awareness regarding the issues in the field radioactive waste management system in Bosnia and Herzegovina.

For the successful implementation of these activities SRARNS needs to collaborate with large number of interested parties which include governmental institutions on all governmental levels of Bosnia and Herzegovina, as well as non-governmental organizations.

Nevertheless, two groups of interested parties must be recognized as the main key players along with SRARNS. One group is governmental institutions which shall adopt their respective legal framework, if needed. The second group is general public with a special focus on the local community whose opinion will be taken in consideration.

Having in mind the governmental and administrative complexity of Bosnia and Herzegovina, well-coordinated cooperation of these two groups with SRARNS is of utmost importance in the process of implementing the activities for radioactive waste management system. In addition, previous activities regarding the radioactive waste management system in Bosnia and Herzegovina have shown very low awareness of the importance on this issue by both targeting groups. The first group does not recognize its role in this management system, as well as the general opinion of this group is that SRARNS should be solely responsible for this management system. As for the second group the low safety culture makes a big impact on acceptance of the needs related to the radioactive waste management system, especially since Bosnia and Herzegovina is non-nuclear country and the general opinion of this group prevails the opinion that those are the issues of nuclear countries. The second group is more sensitive to these issues since "Trgovska gora" activities.

Even though there is a multi-governmental working group responsible for finding the location of the central storage facility for RAW, there is nevertheless their huge need for cooperation among all interested parties. Therefore, SRARNS shall be responsible to create a key message for the first group, which together shall also create the message to the second group with the aim to familiarize it with the needs and obligations of Bosnia and Herzegovina to the international standards which regulate the RAW management system.

Design and construction of facilities – Article 14

Requirements for the storage facility for radioactive waste.

The storage facility for radioactive waste must be purposely designed and constructed for radioactive waste management.

The storage facility for radioactive waste must be designed and constructed in accordance with applicable building regulations.

The storage facility for radioactive waste must be constructed in accordance with a safety case demonstrating radiation safety and security of the storage facility and waste management activities during operations (performance of a practice) and decommissioning of the facility, including an environmental impact assessment in accordance with applicable regulations.

The storage facility must be designed and constructed to meet the following requirements:

a) Sufficient capacity for reception, processing, and holding of the existing and foreseen radioactive waste both from licensed practices and emergencies;

b) Ensuring an appropriate isolation of radioactive waste for the intended storage period;

c) Enabled access to radioactive waste for the purpose of inspection, checking the situation, clearance from regulatory control, or transport.

The operator must analyze and assess the suitability of the storage facility capacities once a year, taking into account the estimated amount of generated radioactive waste and the foreseen operating lifetime of the storage facility.

Assessment of safety of facilities – Article 15

Strategy of radioactive waste management foresees a possibility of construction of a completely new predisposal radioactive waste management facility in Bosnia and Herzegovina. If this option is pursued, a new site will be selected for this facility. Use of an existing facility (that was not used as a radiation facility) with adequate infrastructure, most probably former military facility/area, that can be easily modified to suit the country's needs, will be preferred. Suitability of a site will be evaluated from all relevant aspects and documented in the safety case, which will be approved by the regulatory body. Detailed requirements for the safety case content are given in the Regulation on radioactive waste management.
Guidance on the safety case and safety assessment for predisposal radioactive waste management facilities of Bosnia and Herzegovina is in Annex 4.

Operation of facilities – Article 16

Operation of a facility is governed by its authorization (i.e. license). During the authorization process, inter alia, safety assessment and operational procedures are reviewed and approved. In addition, regulatory authority inspects the facilities in order to check and reassure their safe operation. Operation of facilities more explain in Section H. Existing facilities and past practices – Article 12.

Institutional measures after closure – Article 17

There is no disposal facility in Bosnia and Herzegovina, hence the legislation does not cover measures after its closure. In new draft of Strategy RAWM is defined.

Section I: Transboundary Movement – Article 27

In Bosnia and Herzegovina, import and export of radioactive material need prior approval by SRARNS if its activity is above the exemption limit set in the legislation. Each transport operation of radioactive material needs to be approved by SRARNS, as well. An approval for transport can be issued only to the authorized carriers of radioactive material. Authorization of carriers and import, export and transport operations is governed by the regulation on notification and authorization of radiation practices. Transport operations have to be performed in line with the regulation on the safety of transport of radioactive materials.

According to the policy on the safe management of radioactive waste, import of radioactive waste in Bosnia and Herzegovina is prohibited. Nevertheless, the re-entry of disused sealed sources into its territory is allowed, if the shipment originated from Bosnia and Herzegovina. The returned shipments of radioactive sources have to be approved before entering Bosnia and Herzegovina, as described in the paragraph above.

All previous cases of returned shipments were scrap metal shipments in which a radioactive material was detected abroad. Radioactive material (mainly sealed sources) from those shipments was returned to Bosnia and Herzegovina without major issues, and safely stored. Some more details is given in Section J.

The regulation on radioactive waste management defines that SRARNS will approve export of radioactive waste only if the following requirements are met:

a) The country of destination is a party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;

b) The country of destination has a radioactive waste management and disposal program with objectives representing a high level of safety, in line with international recommendations.

c) The recipient of radioactive waste is authorized for radioactive waste management by the competent authority of the country of destination.

Although not directly connected with Bosnia and Herzegovina's implementation of the obligations of this article, Bosnia and Herzegovina would like to emphasize once more the importance of this article in relation to plans by the Republic of Croatia, presented at the 7th Review meeting of the Joint Convention, to establish a storage facility for radioactive waste low and intermediate activity along the very close border with Bosnia and Herzegovina and Nature Park river Una. The material originates from the nuclear power

plant Krsko in Slovenia, jointly owned by Slovenia and Croatia. Upon establish a storage facility at 2028. Republic of Croatia intends to deposit its amounts of RA waste in the storage facility at the site Trgovska Gora micro location Cerkezovac which is only 3 km away from the town of Novi Grad in Bosnia and Herzegovina with population of about 30,000. Republic of Croatia plans establish near surface disposal macro location at Trgovska Gora at 2055 or any other location on the territory of Republic of Croatia.
The Parliamentary assembly of Bosnia and Herzegovina and the entity parliaments adopted a resolution in which they strongly oppose to the construction of nuclear facility on the Trgovska Gora micro location Cerkezovac. The population living in municipalities in Bosnia and Herzegovina close to the border with Republic of Croatia, and near the Nature Park river Una also expressed its discontent with planned constructions of the nuclear facility for radioactive waste in its surrounding area. The local community from the Bosnia and Herzegovina territory near the planned site is unanimously against this project due to, among other things, lack of detailed information about the project. Republic of Croatia did not follow article. 13 (iv) of JC when it was defining the location for proposed facility
In addition, these activities in Croatia have created additional obligations to the Bosnia and Herzegovina's regulatory agency, and it is necessary to strengthen the SRARNS capacities in this sense provided that Croatia continues to implement the project.

Section J: Disused Sealed Sources – Article 28

Bosnia and Herzegovina does not produce/manufacture radioactive sources and all radioactive material or sources used in the country are imported, mostly from European countries. A condition imposed to the licensees during the authorization procedure is to return any disused source to the supplier/manufacturer. Details of the regulatory framework are reported in Sections B and E.

Disused sealed radioactive source (DSRS) is recognized as such in the legislation and defined as: A radioactive source that is no longer used, and is not intended to be used, for the practice for which an authorization has been granted.

The authorization holder in possession of a high-activity source have an obligation to return the high-activity disused source to the contracted manufacturer or transfer the source to another authorized holder or to a storage facility without any delay and within six months at the latest from the day of terminating the use of source. The authorization holder in possession of a high-activity source must promptly notify SRARNS of the date of terminating the use of such source.

DSRS are not „formally" called radioactive waste but will be considered as radioactive waste if they are to be disposed of in the country, i.e. if they are not going to be returned or exported for recycling. This is defined in the Regulation on radioactive waste management.

DSRS in Bosnia and Herzegovina are stored in two temporary central storage and six industry interim storage locations and one Clinical Hospital location around the country (listed in Annex 1), in various storage conditions – from poor to acceptable. The specific inventories of DSRS in these locations are very different, but are well documented. Six locations and one Clinical Hospital are end-user locations where only end-user DSRS are stored. For each storage location, a different storage principle was followed, from abandoning sources in their working positions after factory bankruptcy, up to partially performed conditioning. Two locations were serving as temporary central storage facilities, operated by technical services. One of the temporary central storages has been closed since 2009, whilst the other storage is still in use as the only active storage location in Bosnia and Herzegovina for emergency situations. The Rakovica facility is licensed according to the regulation on radioactive waste management. Institute of public health Federation of Bosnia and Herzegovina Operator prepared documentation and the Safety Case of Facility Rakovica to SRARNS. This facility is located near Sarajevo and operated by the Radiation protection center of Institute of public health Federation of Bosnia and Herzegovina.

A long term central storage facility has not yet been established in Bosnia and Herzegovina. The reason for exploring a possibility to build a new predisposal facility for long term storage of DSRS and radioactive waste was due conditions in the existing facilities. The existing conditioning and storage facility near Sarajevo is being deemed to be unsuitable for prolonged use due to several safety issues (e.g., located in forested surroundings, lack of a stable water supply, surfaces which could not be easily decontaminated), unless significantly upgraded.

Although the detailed inventory of sealed radioactive sources (both in use and disused) exists in the country, there is an increased probability of orphan sources detection due to 270 old lightning rods with sealed radioactive sources installed on various buildings, some of which are abandoned or destroyed. If a sealed radioactive source from a lightning rod is detected, sometimes it is not possible to track it back to the owner since the state register does not contain serial numbers of all sealed sources.

The area of orphan sources is further regulated by the regulation on control of high activity sealed radioactive sources and sources out of regulatory control, and the supplementary guidance for responding in the case of finding of an orphan source. The regulatory framework in Bosnia and Herzegovina establishes the preventative and reactive measures to be implemented in the event of loss or theft of a radioactive source and, more generally, establishes rules aimed at reducing the risk of radioactive sources being abandoned and which could lead to accidental exposures of individuals.

Each user of a radioactive source is required to establish a system that allows the inventory of the sources to be updated at any time. Additionally, each user of the sources must immediately notify SRARNS in the case of loss, theft or unauthorized use or damage of a source. If necessary, actions are conducted (intervention, investigation) in order to recover the lost or stolen source. Despite the processes and features in place to prevent them, incidents or accidents involving radioactive sources may occur. On average, the number of orphan sources (all were sources from lightning rods) detected in the last few years was in average three cases per year, mainly at border points or at scrap metal yards. While the activity of these detected sources was small, the operator organization was deployed by the order of SRARNS inspector to recover those sources.

The costs of detection, remediation, storage, transportation and all other actions required to place the orphan source under regulatory control, are the responsibility of the most recent authorized owner of that source. In the event that an orphan source is detected at the border during import or export of goods, the exporting/importing company is required to pay the costs; however, if it is not possible to determine the owner of the source, the costs shall be paid from the budget of SRARNS.

Section K: General Efforts to Improve Safety

The first step towards the improvement of safety is publication of the regulation on radioactive waste management in 2015 and its full implementation. Details of this new regulation are given in the Section H. The regulation introduced the safety case development for radioactive waste management facilities and safety assessments for smaller interim storage facilities. These documents should identify the safety shortfalls and actions to overcome them for each existing site. All future conditioning activities will have to be justified by the safety assessment and safety case, as well. Furthermore, Bosnia and Herzegovina considers conditioning of the sealed sources to be an important step towards the final goal – all sources in the country conditioned, characterized and stored in a single storage location, ready for disposal.

The efforts to improve situation in the area of DSRS interim storage facilities in the country during the previous period were not very successful. The implementation of the measures described in the following paragraph will be a priority for Bosnia and Herzegovina.

Bosnia and Herzegovina plans to reduce the number of interim storage facilities in near future. Due to the limited storage space of these facilities, consolidating the DSRS in the country to a single location. This is partly due to an additional significant number of sources anticipated to be stored in the near future at these locations (sealed sources from smoke detectors which have recently been dismantled and 270 sources from lightning rods that are still on their old working positions).

In support of this activity, a conditioning plan for some of those locations has been prepared in close cooperation with all stakeholders, considering site characteristics, safe practice and taking into account specific financial and political circumstances. This includes volume reduction by disassembling sources from the original working containers, separation of non-radioactive material from sealed sources, source characterization, and packaging for transport to the central storage facility. In addition, some locations contain a certain number of Am/Be and Pu/Be neutron sources. These sources can be disassembled from their working containers, packaged in specialized neutron containers and transported.

Bosnia and Herzegovina is exploring possibilities to return to the supplier or export for reuse or for recycling one sours category 2 or 3 new Co-60 with initial activity of 22.2 TBq in year 1990. The source is currently stored in its original working container in RWSF.

While the national strategy alludes to the disposal of all radioactive waste according to the policy, it does not define the details of a disposal facility or programme. This shortcoming in the Strategy is addressed in draft new strategy of RWM.

Establishment of the Bosnia and Herzegovina Centralized Radioactive Waste Storage Facility has two options: namely upgrade of the existing Rakovica storage facility or establishment of a new one at Sreberenik site.
Considering the outcome of the simplified airplane crash analysis presented it was concluded that both sites are to be subject for further airplane crash analysis that will be carried out.
The critical part of the facility in case of both options would be Storage Building that would need to withstand potential airplane crash. In case of the RWSF it would need to be upgraded with newly built well-type storage that will protect radioactive sources from potential airplane crash. In case of the SWSF, the tunnel that has 70 cm concrete walls and is embedded inside the hill, protection against airplane crash will likely be ensured by already existing structures.

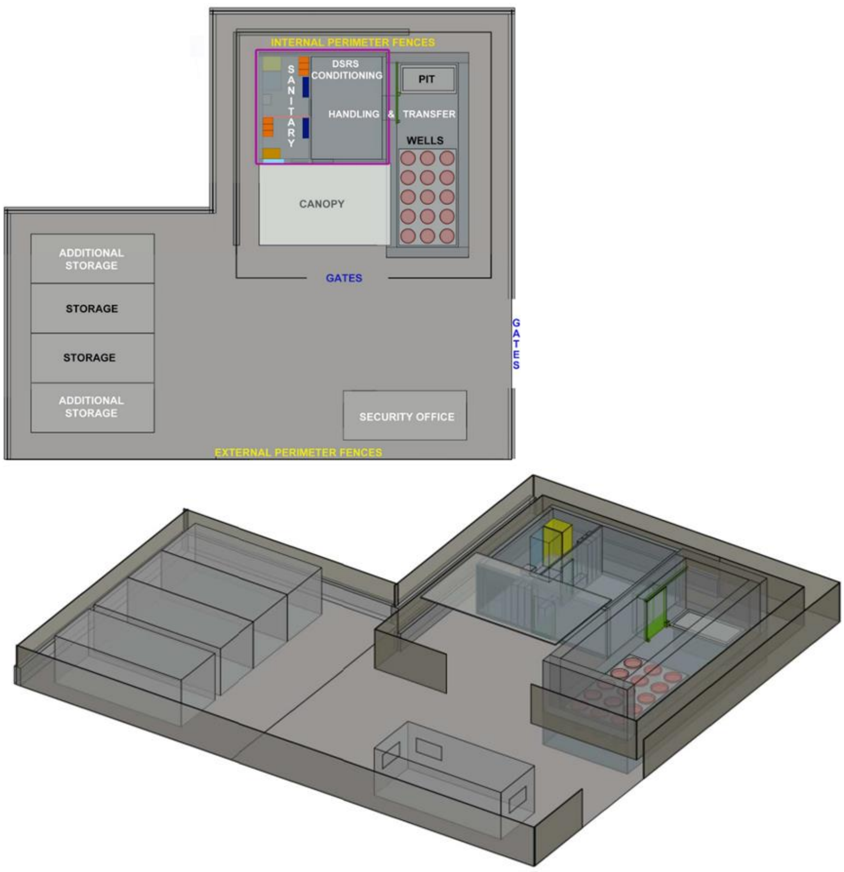

Figure 9: Upgraded RWSF Rakovica generic layout & 3D model

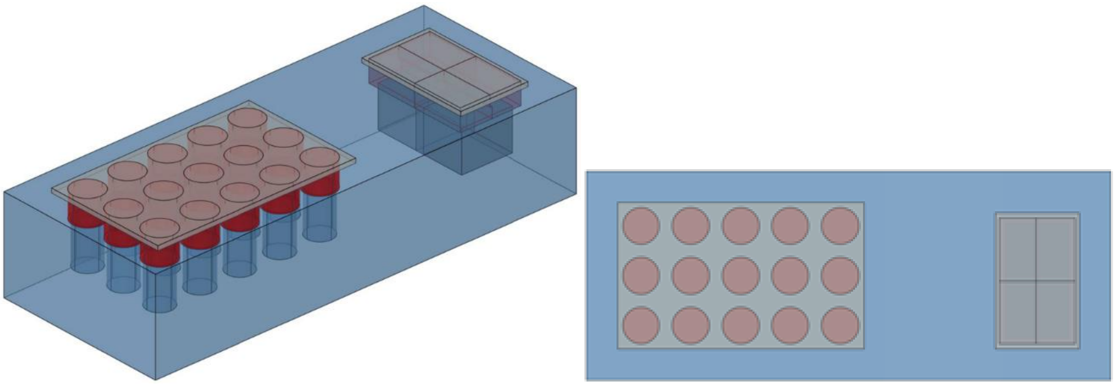

Figure 10: 3D model & top view of the SF with storage pit and wells Upgraded RWSF Rakovica

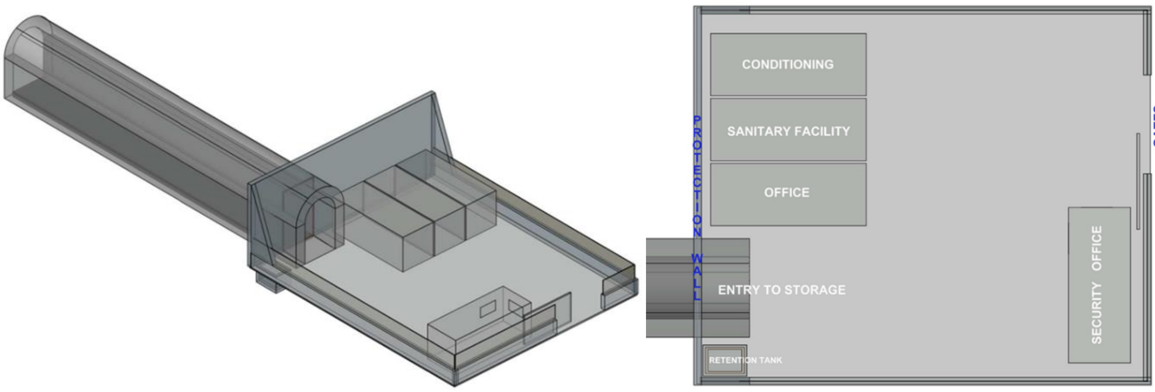

Figure 11: Proposal of Technical Solutions for Establishing New SWSF at Srebrenik Site (SWSF generic layout and SWSF structures and modules)

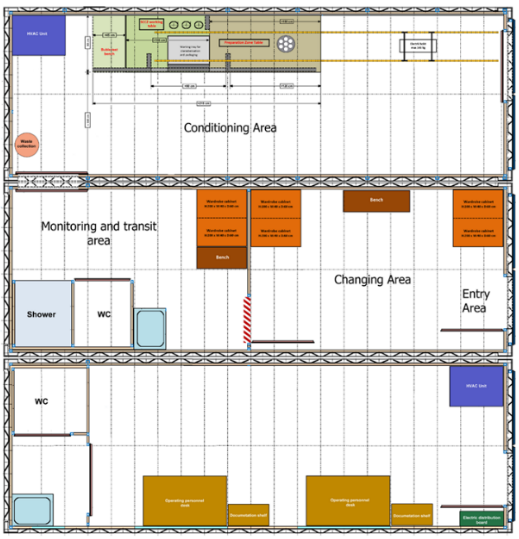

Figure 12: Layout of container based-facilities SWSF

Section L: Annexes

Annex 1: List central and interim factory storage facilities in Bosnia and Herzegovina

1. Rakovica Central temporary storage facility, Sarajevo
2. Rudi Cajavec factory, Banja Luka
3. Iron ore mine Omarska, Prijedor
4. Alumina factory Birac, Zvornik
5. Elektrobosna factory, Jajce
6. Cement factory, Kakanj
7. Mittal steel factory, Zenica
8. Energoinvest industrial radiography, Sarajevo
9. University clinical center Sarajevo

Locations with less than 4 sources stored (lightning rods, nuclear gauges, old industrial radiography cameras)

10. Elektrobosna factory, Jajce
11. Ilios, Istocno Sarajevo
12. Veterinary faculty, Sarajevo
13. Swisslion, Trebinje
14. Bigeste, Ljubuski
15. Garo, Visoko
16. Tehnicki remont, Bratunac
17. Bosnaplod, Brcko

Location with a disused LDR brachytherapy device Cs-137 (36 sources in 1 device)

University clinical center Sarajevo, Sarajevo

Annex 2: Overview of the inventory

Table 1. Current inventory unprocessed radioactive waste/DSRS in RF

Source	Description	Nuclide	A1	Date	NT	Contact dose rate (µSv/h)	Categ ory
INV-IND001-004	BS, gauge	Co-60	1,00E+10	1970	4	N/A	5
INV-IND005-010	BS, gauge	Cs-137	2,00E+10	1970	6	N/A	4
INV-NEU003	WS, gauge	Am-241/Be	1,48E+09	11984	1	x	4
INV-IND011	BS, gauge	Cs-137	2,92E+08	1984	1	75	4
INV-IND012	WS, gauge	Am-241	1,11E+10	1981	1	100	5
INV-IND013-019	WS, gauge	Co-60	3,70E+09	1990	7	9	4
INV-IND020	WS, gauge	Cs-137	7,40E+09	1990	1	1,5	4
INV-IND021-024	WS, gauge	Co-60	1,11E+09	1979	4	10	5
INV-IND025	WS, gauge	Co-60	3,70E+07	1979	1	2	5
INV-IND026-027	WS, gauge	Cs-137	3,70E+08	1989	2	8	5
INV-IND028-029	WS, gauge	Kr-85	1,85E+10	1984	2	30	5
INV-IND030-031	WS, gauge	Cs-137	9,25E+08	1974	2	30	4
INV-IND032	BS, gauge	Am-241	3,70E+10	1990	1	40	4
INV-IND033	BS, gauge	Kr-85	1,85E+09	1990	1	50	5
INV-IND034-037	WS, gauge	Cs-137	7,40E+09	1990	4	1	4
INV-IND038	WS, gauge	Am-241	1,11E+10	1981	1	2	4
INV-IND039	WS, gauge	Cs-137	7,40E+09	1990	1	N/A	4
INV-IND040	WS, radiography	Ir-192	1,85E+12	2006	1	17	5
INV-IND041	WS, radiography	Ir-192	1,85E+12	2009	1	17	5
INV-IND042	WS, radiography	Ir-192	1,85E+12	2008	1	17	5
INV-IND043-044	WS, gauge	Cs-137	5,50E+09	2009	2	20	4
INV-IND045-050	WS, gauge	Co-60	1,45E+10	1986	6	200	5
INV-IND051-055	WS, gauge	Co-60	1,45E+10	1986	5	150	5
INV-KAL001	WS, calibration	Co-60	2,22E+16	1990	1	3	2
INV-KAL002	WS, calibration	Co-60	2,55E+11	1990	1	13	4
INV-KAL003-1	WS, calibration	Co-60	2,83E+12	1990	1	5	3
INV-KAL003-2	WS, calibration	Co-60	2,74E+11	1990	1	5	4
INV-KAL003-3	WS, calibration	Co-60	4,63E+10	1990	1	5	4
INV-KAL003-4	WS, calibration	Co-60	9,99E+09	1990	1	5	5
INV-KAL003-5	WS, calibration	Co-60	1,26E+09	1990	1	5	5
INV-KAL003-6	WS, calibration	Co-60	1,60E+08	1990	1	5	5
INV-KAL003-7	WS, calibration	Co-60	1,60E+07	1990	1	5	5
INV-KAL004	WS, calibration	Co-60	5,55E+07	1990	1	4	5
INV-KAL005-009	WS, calibration	Sr-90	3,70E+07	1990	5	4	5
INV-MED001	WS, brachytherapy	Cs-137	6,66E+07	1988	45	6	4
INV-MED002	WS, brachytherapy	Co-60	5,30E+08	2006	3	12	5
INV-MED003	SS, medicine	Co-60	7,70E+06	2006	3	6	5
INV-MED004	WD, medicine	Ra-226	2,30E+07	2006	1	200	5
INV-MED005	WD, medicine	Ra-226	2,30E+07	2006	1	180	5

INV-MED006	WD, medicine	Ra-226	8,45E+06	2006	1	100	5
INV-NEU001	BS, neutron	Am-241/B	3,70E+10	1972	1	4	4
INV-NEU002	BS, neutron	Am-241/Li	3,70E+10	1972	1	11	4
INV-RLR-Co-60	BS, RLR Co-60	Co-60	7,40E+09	1980	11	N/A	5
INV-RLR-Eu-152	BS, RLR Eu-152	Eu-152	1,48E+10	1980	102	N/A	4
INV-CHKSRC	BS, Sr-90	Sr-90	1000	1990	685	N/A	5
INV-Smoke detector WD	WD, Smoke detector, Am-241	Am-241	74400	1990	1932	N/A	5
INV-Smoke detector BS	BS, Smoke detector, Am-241	Am-241	74400	1990	667	N/A	5

BS-Barte source, WS-Working shield, WD-Working device, SS-Storage shield; Categorized according to current activities

Waste	**Radionuclide**	**Activity (GBq)**	**Qty**
Depleted uranium ammunitin metalic fragments	U-238,U-235(<0.7%), U-234	14.8 Bq/mg	30 kg
Jet engine metalic fragments	Th-232	160 Bq/g Th-232 1500 Bq/g daughter products	100 kg
Radioluminiscent dial	Ra-226	≈25 MBq/source	2 units
Radioluminescent personnel markers	Ra-226	≈2 MBq/source	4 units
Radioluminiscent markers	H-3	Unknown	100 units

Table 2. Conditioned radioactive waste stored in RF

Container	**Nature of contents**	**Radionuclide**	**Type of source**	**Type of waste**	**Activity (GBq)**	**Contact dose rate (mSv/h)**	**Drum description**
1998-1	Cemented	Ra-226	Radium paint*	Solid	2.3	1.2	200 L, steel, lidded
1998-2	Cemented	Ra-226	Secondary waste during conditioning process (contaminated materials)	Solid	Unknown	0.9	200 L, steel, lidded

*- 31 glass bottles, 80x20 mm, with 20 g of radium paint containing 2 mg Ra-226 each. Total amount of Ra-226 is 62 mg.

Table 3. overview of the storage DSRS in the interim storage at the territory of Bosnia and Herzegovina

IAEA category	**Application**	**Interim store at the user premises**	**Centralized facilities**
1	Total	0	0
2	Calibration		
	Total	0	4
3	Calibration		4
	Gauges	1	
	Total	1	4
4	Gauges	117	40
	Brachytherapy (LDR)		6
	Calibration		7
	Total	117	53
5	Gauges	19	8
	Calibration		10
	Check sources		1028
	Smoke detectors		2847
	Total	19	3893

Table 4. Overview of other radioactive waste

- Fourteen standards 200 L barrels with low contaminated concrete and sand with Cs-137;
- For barrels 55,3 kg with U3O8 used as shielding material.

Annex 3: List of international treaties and conventions ratified by Bosnia and Herzegovina

1. Convention on Nuclear Safety, in force as of 19.9.2010.
2. Statute of the International Atomic Energy Agency and the Amendments to Article 6. and Article 14. of the Statute ("Official Gazette of B&H - International Treaties", No. 4/13),
3. Treaty on the Non-Proliferation of Nuclear Weapons ("Official Gazette of SFRY" No. 10/70),
4. Agreement with the International Atomic Energy Agency (IAEA) on the application of safeguards in connection with the Treaty on Non-Proliferation of Nuclear Weapons ("Official Gazette - International Treaties of B&H", No. 3/13);
5. Additional Protocol to the Agreement with the International Atomic Energy Agency (IAEA) on the application of safeguards in connection with the Treaty on Non-Proliferation of Nuclear Weapons ("Official Gazette of B&H - International Treaties", No. 10/13),
6. Revised Supplementary Agreement concerning the provision of technical assistance by the International Atomic Energy Agency, to Bosnia and Herzegovina ("Official Gazette - International Treaties" No. 2/10);
7. Convention on early notification in case of a nuclear accident ("Official Gazette of SFRY - International Treaties" No. 15/89);
8. Convention on Assistance in the case of a nuclear accident or radiological emergency ("Official Gazette of SFRY - International Treaties" No. 4/91);
9. Convention on the physical protection of nuclear material ("Official Gazette of SFRY - International Treaties" No. 9/85);
10. Amendments to the Convention on the physical protection of nuclear material ("Official Gazette - International Treaties" No. 3/10);
11. International Convention on the suppression of terrorist bombings ("Official Gazette - International Treaties" No. 7/03);
12. International Convention on the suppression of acts of nuclear terrorism (UNTS - vol. 2445, p. 89);
13. Vienna Convention on Civil Liability for Nuclear Damage ("Official Gazette of SFRY - International Treaties" No. 5/77);
14. Protocol on Amendments to the Vienna Convention on Civil Liability for Nuclear Damage ("Official Gazette - International Treaties" No. 16/12);

15. The Convention on Information availability, public participation in decision-making and access to justice in matters relating to the environment (Aarhus Convention) ("Official Gazette - International Treaties" 8/08).

Annex 4: Guidance on the safety case and safety assessment for predisposal radioactive waste management facility in Bosnia and Herzegovina

1. Introduction

Scope

1.1. The Guidelines on Safety Case and Safety Assessment for Predisposal Radioactive Waste Management Facilities (hereinafter "these Guidelines") provide recommendations on the preparation of safety cases and conduct of safety assessments for predisposal radioactive waste management facilities.

1.2. The recommendations provided in these Guidelines constitute the minimum expectations of the State Regulatory Agency for Radiation and Nuclear Safety (hereinafter "the Agency") from the operators to comply with the safety requirements prescribed under the *Regulations on Predisposal Management of Radioactive Waste*.

1.3. The operators are also expected to apply the latest international safety standards and guidelines that are relevant for the predisposal management of radioactive waste and the development and operation of predisposal radioactive waste management facilities.

Purpose

1.4. These Guidelines are addressed to the license applicants for development and operation of predisposal radioactive waste management facilities as well as to the license holders for development or operation of such facilities (hereinafter "operators").

1.5. The provisions of these Guidelines are applicable to the predisposal management of all classes and categories of radioactive waste generated in Bosnia and Herzegovina.

2. Safety Assessment

2.1. Safety assessment is the process of evaluating the safety of a predisposal radioactive waste management facility by quantifying its potential impact on human health and the environment. This process should be conducted in a systematic manner, using a graded approach, proportional with the associated hazards, the complexity of the facility and the characteristics of the radioactive waste under consideration. The safety assessment should include the quantification of the overall level of safety of the facility and the analysis of the associated uncertainties. The methodology used for the safety assessment should be systematic and the assessment should address all aspects relevant to protection and safety.

2.2. The safety assessment is not required to be performed at the same level of detail at all stages of the facility development and operation, since not all the necessary data will be available from the beginning; however, the safety assessment should be updated at least before the beginning of each new stage, or periodically during the operational stage, taking into consideration new available data, as well as the feedback from the operating experience.

2.3. The safety assessment process should include the following steps:

a) Specification of the assessment context;
b) Description of the predisposal radioactive waste management facility and of the radioactive waste;
c) Development and justification of scenarios;
d) Formulation of models, parameterization;
e) Performance of calculations, evaluation of results;
f) Analysis of safety measures and engineering aspects, and comparison with safety criteria;
g) Independent verification of safety assessment results;
h) Review and modification of the assessment, iteration.

2.1. Safety assessment context

2.1.1. The specification of the safety assessment context should include the specification of the following aspects:

a) the purpose and scope of the safety assessment;
b) the relevant regulatory framework together with the identification of the relevant safety criteria;
c) the assessment approach, under which the assessment methods selected to conduct the safety assessment should be specified and justified;
d) the safety assessment endpoints;
e) the time frames for the safety assessment.

Safety assessment purpose and scope

2.1.2. The safety assessment will be developed together with the facility and will be used as a basis for authorisation by the Agency and other decisions relating to, for example, the design, supporting research work or site characterization activities. The context for each revision of the safety assessment should be set out clearly and should be updated as necessary and appropriate for subsequent revisions of the safety assessment.

2.1.3. The purpose of each revision of the safety assessment will depend on a number of factors, such as the planning of the facility development, the stage of development of the facility, and whether the safety assessment is being submitted to the Agency as part of the licensing process. For each revision of the safety assessment, the operator should provide a clear description of its purpose, which, depending on the stage of development of the facility, could include:

a) Site selection;
b) Demonstration of the safety of the facility or activity;
c) Periodic reassessment as required by the applicable regulations;
d) Application to modify the facility or activity;
e) Shutdown and decommissioning of the facility.

2.1.4. The scope of the safety assessment should be clearly defined. It should identify whether the safety assessment considers an entire facility or a single activity within a larger facility and it should also consider site boundaries and interfaces with neighbouring activities and facilities. In case of step by step development of the facility, the scope of the safety assessment should provide a clear identification of the relevant stage in the facility's lifetime, how the safety assessment has changed from previous versions, and how it will support future revisions.

Relevant regulatory framework

2.1.5. The approach to demonstration of safety refers to the safety objectives and safety principles that must be applied and the regulatory requirements that must be met. The regulatory framework that governs the assessment of safety should be documented, and the safety assessment should be conducted in a manner consistent with that framework. The safety criteria established in the regulatory framework and by the Agency are required to be also specified. Safety requirements other than safety criteria, as well as other requirements relating to the safety assessment (e.g. industrial safety criteria, environmental criteria, clearance criteria and criteria for release of the site from regulatory control) should be identified and specified too.

Safety assessment approach

2.1.6. The approach taken in conducting the safety assessment should be presented in the context of the safety assessment. The safety assessment should be performed using an appropriate selection of approaches that, when used in a complementary manner, can increase confidence in the safety of the facility. The different approaches that can be considered include:

a) reasoned arguments,
b) the use of simple conservative models,
c) probabilistic and deterministic approaches, and
d) the use of more complex and more realistic models.

2.1.7. For complex facilities, a combination of probabilistic methods and deterministic methods is recommended. While such combinations may contribute to increased confidence in the outcomes of the assessment, for simple facilities qualitative analyses might be sufficient.

2.1.8. Both conservative and realistic calculations might be necessary in a safety assessment and both approaches can be used to increase confidence in the safety of the facility. Conservative models can be used, especially in the early phases of assessment, for rapid estimation of the performance of the facility. Simple conservative models may also be used to increase confidence in the results obtained with more complex models. The decision to use a conservative approach, a realistic approach or both, have to consider the objective of the assessment, the regulatory requirements, the availability and reliability of data, the complexity of the site and the facility, and the available resources. If the safety assessment is to be used for optimizing the design of the facility or for demonstrating a detailed understanding of its behaviour (which is required for obtaining the operation license), the safety assessment should be as realistic as possible, given the availability of relevant and reliable data, including radiological and environmental monitoring results, operating experience and information on historical events relevant to safety (at the facility or at similar facilities elsewhere).

Safety assessment endpoints

2.1.9. A description and justification of the selected end points corresponding to the associated regulatory safety requirements and criteria should be provided. The safety assessment end points can include:

a) End points considered for the radiological impact, such as dose or risk;
b) Other safety indicators such as dose rates, radionuclide releases, concentrations of radionuclides in the environment, concentrations and releases of non-radiological contaminants and impacts on non-human species.

2.1.10. A description of how the assessment end points will be used, for example, to determine compliance with radiological and/or environmental standards is also needed.

Time frames for the safety assessment

2.1.11. The time frame for the safety assessment is the longest period considered in the calculations. The reasons behind the selection made for the purposes of the safety assessment should be explained and justified.

2.1.12. The receptors (persons or groups receiving a radiation dose from the facility or with a risk of exposure) associated with each of the various end points should be clearly specified and described. The use of a range of potential receptors should also be considered, in case there is more than one group which could be exposed. For the assessment of public exposure, a representative person should be defined, as required in the Regulation on radiation protection for occupational and public exposure.

2.2. Description of the predisposal radioactive waste management facility and of the radioactive waste

2.2.1. The description of the facility should include all the information and knowledge about the facility and the activities to be carried out, and should provide the basis on which the safety assessment is conducted. The description of the facility and the radioactive waste should contain, depending on the type of the facility, information on the following aspects:

a) The site conditions;
b) A description of the predisposal system (the facility and the activities);
c) The radioactive waste inventory to be processed or stored.

Site conditions

2.2.2. The site conditions and the associated events, both natural and human induced, that could influence safety should be identified and described. The site characteristics are needed as in input to the design and should refer to the range of conditions under which the facility will be operated. All site conditions, processes and events having relevance for safety should be identified and considered, in accordance with a graded approach. The "normal situation" (or average conditions) should be determined, together with any other extreme, but credible, events that may impact the safe operation of the facility.

Predisposal system description

2.2.3. The facility design and the fundamental assumptions upon which the design is based should be addressed in the safety assessment, therefore the system description should include:

a) a full description of the structures, systems and components of the facility and their importance for safety;
b) the quantity and characteristics of the radioactive waste to be handled at the facility;
c) the range of conditions under which the facility may operate;
d) the hazards to which the facility may be exposed;
e) the required performance criteria.

2.2.4. The fundamental design requirements that have been applied and how the resulting design reflects these requirements should also be considered. The fundamental design requirements should address the need to ensure an adequate degree of redundancy, diversity, reliability and tolerance of faults, and the need to ensure that any failures that might occur are limited in scope and, to the extent possible, will have limited consequences.

2.2.5. Under the safety assessment, the design should be examined in order to determine whether the design, in conjunction with operation at the facility, incorporates adequate measures to prevent accidents and to limit their consequences. The flexibility of the design to accommodate changes in operating conditions, the technology used and the planned decommissioning should also be examined.

2.2.6. In case the facility is subject to the system for accounting and control of nuclear material, any provisions that are put in place for this purpose should be assessed from a safety point of view and any conflicts (such as access restrictions to areas or material) should be resolved from the design stage.

2.2.7. In addition to issues relating to the design and construction, the safety of a facility also depends on operational aspects, such as operating and maintenance procedures, controls and monitoring. The system description should therefore include information about:

a) the organizational structure of the operating organisation;
b) the staffing of the operator;
c) the required personnel competencies.

Radioactive waste inventory

2.2.8. The description of the radioactive waste should include data on the types of radioactive waste to be processed (pretreated, treated and conditioned) or stored, as well as on radioactive material that is to be cleared or discharged from the facility, as follows:

a) the volume and form of the waste;
b) the radionuclides of concern;
c) the radioactive content;
d) the presence of fissile materials;
e) other physical, chemical and pathogenic properties.

2.2.9. Secondary radioactive waste that may arise from the operation of the facility should also be included in the description of the radioactive waste.

2.2.10. Variations in the expected characteristics of incoming radioactive waste should be considered, particularly with respect to their influence on the potential for anticipated operational occurrences and design basis accidents at the facility.

2.3. Development and justification of scenarios

2.3.1. Safety assessment scenarios should be defined as postulated (or assumed) sets of conditions and/or events that may lead to human exposure or environmental contamination. A scenario may represent a range of similar situations reflecting either certain conditions arising during normal operation of the facility or as the consequence of a specific event leading to deviations from normal operation conditions. The safety assessment scenarios should be defined taking into consideration all relevant existing and potential hazards arising from the facility, their interrelations and evolution over the lifetime of the facility.

2.3.2. In order to develop the safety assessment scenarios and to justify the selection made, the following steps should be applied, in an iterative manner, in order to identify normal operation and anticipated operational occurrences and accident conditions that could lead to the exposure of workers and members of the public, or adversely impact the environment:

a) identification of potential hazards;
b) screening of hazards;
c) identification of scenarios.

Identification of hazards

2.3.3. For the identification of potential hazards, the status of the planned operations during normal conditions, maintenance and recovery from failures should be considered, together with how failure of one operation can affect associated operations. Hazards that could occur as a consequence of human error should also be considered, as well as non-radiological hazards (such as chemical, toxic or industrial) that may affect the radiological safety (such as fires) or that are requested by other national legislation. Software reliability should also be covered in the hazard identification process, in case the facility will include remotely operated components.

2.3.4. The identified hazards should be further quantified and screened. Hazards lacking the potential to cause harm to human health and/or the environment to a degree that exceeds the relevant safety requirements or criteria, or which cannot be realized given the scope of the facility, can be screened out from the subsequent hazard analysis. During the future reviews of the safety assessment, the screening arguments should be reviewed to check if they remain valid.

Screening of hazards

2.3.5. The identified hazards should be quantified with no credit taken for any protective or mitigatory safety measures to be used, except for passive features of the facility (e.g. walls for shielding, engineered safety features) that are not affected by the initiating event. Hazards with the potential to cause significant harm through any identified pathway or events with a high probability of occurence should be further considered for analysis.

2.3.6. The hazards screening process should consider all releases of radioactive material and exposures in normal operation, anticipated operational occurrences and accident conditions.

2.3.7. The hazards screening process should consider all potential exposure pathways to workers, such as:

a) external exposure from contamination and/or activation of the structures, components, buildings, surfaces, etc. in the facility or from radioactive material (e.g. sealed sources, radioactive waste packages, direct radiation from gamma emitting radionuclides);
b) inhalation or ingestion of airborne releases (particularly gases, aerosols and particulates) during operation of the facility or activity, or following an accident;
c) dose to the skin arising from radioactive material deposited on skin or clothing;
d) combination of contamination and mechanical injuries (e.g. contamination of wounds).

2.3.8. The hazards screening process should consider, wherever applicable, all potential exposure pathways to members of the public and releases to the environment. In addition to the pathways listed in the previous paragraph for workers, the potential for off-site exposure pathways through water, via airborne releases and/or via the food chain should be considered for the members of the public.

Development of scenarios

2.3.9. Safety assessment scenarios for screened hazards should be generated in a systematic manner, by the identification of postulated initiating events through which harm could occur, in particular:

a) External initiating events including:
    i. natural events, such as adverse meteorological conditions (wind, snow, rain, ice, temperature, flood, lightning), earthquakes or biological intrusion;
    ii. human-induced events (aircraft crashes, with or without subsequent fires, explosions, fires, loss of electrical power or other services, unauthorised access);
b) Internal initiating events at the facility or the site (fire, explosions, collapse of structures, leakages or spillages, failure of ventilation, drops of heavy loads, failure of protective measures such as shielding or personal protective equipment);
c) Human initiating events (operator errors and violations, misidentifications, performance of incompatible activities, actions taken during the evolution of an accident to mitigate the consequences of the accident).

2.3.10. The identification of initiating events and their evolution should be carried out using appropriate techniques (hazard and operability analysis, event tree analysis or fault tree analysis) and sources of information (checklists, expected dose rates for the facility or activity, inventories of radioactive waste, feedback from other facilities or activities). A list of postulated initiating events to be considered for predisposal radioactive waste management facilities is given in Annex I.

2.3.11. Safety assessment scenarios should be defined for normal operational conditions, anticipated operational occurrences and accidents. The safety assessment should address the consequences arising from all normal operational conditions and the frequencies and consequences associated with all anticipated operational occurrences and accident conditions. The degree of detail of the assessment should be commensurate with the magnitude of the radiation risks associated with the facility, the frequency of the events included in the assessment, the complexity of the planned operations and the uncertainties affecting the calculations.

2.3.12. The scenarios for normal operation should address all conditions under which the systems and equipment of the facility will be operated as expected, with no internal or external challenges. This includes all aspects of operation for which the facility is designed to operate in the course of normal operation and maintenance over the lifetime of the facility. The normal operation scenarios should be defined with the aim to assess whether the activity can be carried out safely or the facility operated safely under normal conditions, and in particular:

a) if the radiation doses to workers and members of the public will be within the prescribed limits and constraints and will be maintained as low as reasonably achievable;
b) If the planned discharges will be within the authorised limits;
c) If the elements of defence in depth will be maintained and that adequate safety margins will remain at all times.

2.3.13. Anticipated operational occurrences are operational processes deviating from normal operation that are expected to occur at least once during the operating lifetime of the facility, but which, if appropriately designed, do not cause any significant damage to items important to safety or lead to accident conditions. A design basis accident is an accident condition against which a facility is designed according to established design criteria, and for which the damage to the radioactive waste inventory and the release of radioactive material are kept within authorized limits. Design basis accidents have a lower frequency than anticipated operational occurrences; they are not expected to occur during the lifetime of the facility but are considered in the design of the facility. The safety assessment should identify the anticipated operational occurrences and accident conditions. This should include all internal and external events and processes that may impact the physical barriers that confine the radioactive material or otherwise give rise to radiation risks. The assessment should be based on an appropriate grouping and bounding of the events and processes; partial failures of components or barriers as well as complete failures should be considered.

2.3.14. The assessment of anticipated operational occurrences and design basis accidents should provide a demonstration that the design of the facility is such that:

a) The potential for release of radioactive material or loss of shielding is controlled and the safety requirements will be met;
b) Any operational discharges of effluents will remain below prescribed limits;
c) Limiting criteria for design basis accident conditions will be met;
d) The applied radiological limits will not be exceeded;
e) Some or all of the barriers put in place to limit exposures and to limit the release of radioactive material from the facility will maintain their integrity to the extent required.

2.3.15. The analysis of scenarios addressing design basis accidents should be used as a basis for design specifications relating to safety features (e.g. the confinement boundary, the fire protection system, the ventilation system, the cooling system) and the electric power system (if necessary for safety).

2.3.16. Accidents beyond the design basis are those accidents that are not considered as design basis accidents, but are taken into account in the design process of the facility in accordance with best estimate methodology, and for which releases of radioactive material are kept within acceptable limits. Accidents that are beyond the design basis can have different consequences, as follows:

a) Those that fall within the envelope of the conservative acceptance criteria for the design basis accidents (an assessment may be necessary to demonstrate this);
b) Those that exceed the conservative acceptance criteria for the design basis accidents but would not result in significant facility damage or releases beyond discharge limits;
c) Those in which there is significant facility damage, the safety features malfunction and some of the barriers to the release of radioactive material fail or are bypassed ('serious accident').

2.3.17. For the first two categories of beyond design basis accidents (listed in points a) and b) of the previous paragraph), the assessment should aim to quantify a safety margin for the facility and should demonstrate that a degree of defence in depth is provided for this class of accidents, namely that the facility design and operation includes, where reasonably achievable, the following:

a) Measures to prevent the escalation of events into serious accidents, to control the progression of serious accidents and to limit releases of radioactive material, by provision of additional equipment and accident management procedures;
b) Measures to mitigate the potential radiological consequences, by provision of on-site and off-site emergency response plans.

2.3.18. For the assessment of beyond design basis accidents a set of representative fault sequences should be selected, by including additional failures or incorrect operator responses in the scenarios for design basis accidents. The important event sequences that could lead to serious accidents should be identified using a combination of probabilistic and deterministic methods, and sound engineering judgement. The assessment should be carried out using best estimate assumptions, data, methods and decision criteria; if this is not possible, reasonably conservative assumptions should be made.

2.4. Formulation of models, parameterization

2.4.1. After the development of the scenarios, the safety assessment should be carried out. In order to perform the necessary calculations, an assessment model should be developed, with the following components:

a) a conceptual model, which is a representation of the predisposal system under consideration that includes a set of assumptions on the system geometry, the chemical, physical, biological and mechanical behaviour of the system, based on the available information; the conceptual model should provide a description of the facility's components and the interactions between them;

b) a mathematical model, which is a representation of the features and processes included in the conceptual model using mathematical equations; this model will be used for performing the calculations;
c) a computer code, which is a software implementation of the mathematical model that facilitates the performance of the calculations; the computer code may include numerical schemes for solving the equations in the mathematical model.

2.4.2. Specific models may have to be developed for particular processes and/or system components. For the purposes of safety assessment, these models will need to be linked in such a way that it is possible to assess the potential radiological impacts of the facility as a whole. In developing assessment models, it should be ensured, to the extent possible, that:

a) The level of detail and the balance between realism and conservatism in modelling is appropriate for the defined context and the existing knowledge of the predisposal system;
b) The conceptual model provides a reasonable representation of the predisposal system and the mathematical model adequately represents the conceptual model;
c) Any alternative conceptual and mathematical models that have been considered or evaluated are documented in order to provide supporting arguments about the adequacy of the selected models;
d) Appropriate exercises for model verification and validation are conducted and documented to build confidence in the suitability of the model for its intended purpose.

2.4.3. Following the development of the assessment models, they have to be parameterized, by assigning values to the different parameters used in the models. For this purpose, the following aspects should be considered:

a) Parameter values used as inputs to the models and codes used in assessment calculations should be documented (the process of model parameterization should be traceable to data sources);
b) Records should be kept of how site specific and system specific characterization data have been used to derive parameter values used in the assessment calculations;
c) If a probabilistic approach has been used in the assessments, a justification of the selected probability distributions should be provided;
d) If a deterministic approach has been applied, a justification for the conservatism or realism of the selected parameter values used in the calculations should be provided.

2.5. Performance of calculations, evaluation of results

2.5.1. Once the models have been parameterized, they should be used for performing the calculations for the assessment cases corresponding to the different scenarios selected for the assessment, using the conceptual models and the site data and facility design information. Sensitivity and uncertainty analyses should also be performed in order to demonstrate the system understanding, and to show that parameter correlations have been adequately treated.

2.5.2. Sufficient results of the safety assessment should be provided, in order to allow the comparison with the assessment endpoints and with any other selected performance criteria.

2.5.3. The analysis of uncertainties should be an integral part of the dose or risk calculation process and, to the extent possible, the results should be reported as ranges of possible values rather than single point values. For each scenario, it is necessary to deal with uncertainties in the models and the parameter values used for calculations.

2.5.4. Uncertainty analysis should consist in the estimation of the uncertainties in the assessment end points from the uncertainties in the input data and model parameters. Sensitivity analysis should be used to identify the relative importance of each uncertain input parameter to the results of the assessment.

2.5.5. Modelling uncertainties could be analyzed by performing inter-comparisons between alternative models, or between model predictions and empirical observations, or by sensitivity analyses.

2.5.6. Uncertainties could also be treated by using conservative assumptions (e.g. when simplifying the models used) or by assigning conservative values to model parameters. However, for such situations, care should be taken to avoid assessments representing situations that are extremely unrealistic or impossible and, therefore, difficult to interpret, or assigning conservative values to several parameters, which may lead to overly conservative results. The conservatism of the assumptions should therefore be justified in relation to their impact on the assessment end points.

2.6. Analysis of safety measures and engineering aspects, comparison with safety criteria

2.6.1. The results of safety assessment should serve to demonstrate compliance with the regulatory requirements and criteria expressed in terms of effective dose (e.g. individual annual effective doses for normal operation, individual effective doses for single incidents, including accidents) or in terms of risk. To achieve this, the results of safety assessment should be expressed in the same units as the associated safety criteria.

2.6.2. Results indicating that the calculated doses are less than the established dose constraint are not sufficient for the acceptability of the safety case for a predisposal waste management facility, since other requirements have to be fulfilled, as discussed in the following paragraphs.

2.6.3. The quantitative assessment of potential radiological impacts should result in conclusions on the adequacy of the chosen / proposed site, as well as on the intended design of the facility. The conclusions drawn from quantitative assessment should be supplemented by qualitative arguments and assessments. The integrated set of qualitative and quantitative assessment results should be sufficient to demonstrate the adequacy of the site and engineering aspects, compliance of the site and engineering aspects with the relevant safety requirements and that the safety approach set out for the facility is fulfilled.

2.6.4. The engineering analysis should identify where changes to the design could eliminate a hazard or reduce the frequency of occurrence or consequences of an event. The benefit of making the identified changes should be evaluated using the principle of optimization of protection.

2.6.5. The safety assessment should also be used to identify the safety functions and associated structures, systems and components that are relied on for preventing accidents and for mitigating the consequences of initiating events. This should be done by applying appropriate engineering codes and standards, commensurate with the importance of the safety functions (e.g. the consequences of their failure to perform).

2.6.6. The safety assessment should be used to determine whether the existing structures, systems and components are suitable and sufficient to perform their functions during normal operation, anticipated operational occurrences and accident conditions, and whether they will achieve the required control of doses and risks. The safety assessment should also be used to verify that existing structures, systems and components will continue to perform their safety functions for as long as required by the stage of the facility, with account taken of ageing, other degradation mechanisms and potentially invasive maintenance activities.

2.6.7. The safety assessment should be used to identify any safety functions that require new engineered structures, systems and components, and should verify that these will be suitable and sufficient to meet the relevant safety requirements and criteria. The safety assessment should also be used to identify any ongoing engineering requirements that need to be applied during operation (e.g. inspection, maintenance and testing of structures, systems and components) and services that need to be maintained.

2.6.8. The operator should demonstrate that, to the extent possible, the safety of the facility is ensured by passive safety features for the anticipated lifetime of the facility, in particular for the storage of radioactive waste. The assessment of long term safety should take into account the degradation of passive barriers over time. Each safety function should be as independent as possible of the others, in order to ensure that they are complementary and cannot fail through a single failure mode. The safety assessment should explain and provide evidence for the safety functions provided by each barrier and should identify the time periods over which the barriers are expected to perform their various safety functions. The safety assessment should also identify the alternative or additional safety functions that will operate if a barrier does not perform as expected.

2.6.9. The operator should demonstrate that several safety functions have been taken into account in the design of the facility, or that safety is not unduly dependent on a single component or control procedure, or on the fulfilment of a single safety function. The most important safety functions are usually fulfilled by means of passive barriers, such as the physical or chemical properties of the conditioned radioactive waste, the waste package itself or process piping. Active controls can also provide safety functions or contribute to the confidence in passive barriers and safety functions, but these should not be relied on completely to ensure defence in depth.

2.6.10. The safety assessment should take into account the existing levels of defence in depth or should provide evidence of the adequacy of the projected levels of defence in depth, by:

a) Identification of barriers and other safety functions;
b) Explanation of the diversity of such barriers and other safety functions;
c) Explanation of the resilience of such barriers and other safety functions under normal and abnormal conditions;
d) Demonstration that if any single safety barrier were to fail then the safety of the facility would not be unacceptably compromised.

2.6.11. In the safety assessment, particular consideration should be given to internal and external hazards that could have the potential to adversely affect more than one barrier.

2.6.12. Good technical and engineering principles should be applied in order to avoid complex or insufficiently characterized situations, and procedures should be put in place to ensure the application of these principles. The operator should demonstrate 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 adequate for the intended use.

2.6.13. In the safety assessment, consideration should also be given to the reliability of components over the lifetime of the facility. Components should be designed to have a lifetime commensurate with the demands that will be placed upon them. The appropriate design of components should be complemented by an appropriate maintenance program to ensure the continued reliability of the component.

2.6.14. For facilities with long lifetimes, such as storage facilities, it is necessary to use well proven and well documented materials, so that there is confidence that they will last for the lifetime of the facility.

2.6.15. In the case of planned extension of the lifetime of a facility beyond its original planned lifetime, the safety assessment should be updated to address the potential impacts on safety. The update should take into account the degradation of barriers or components, and should be performed well in advance of the end of the original licence validity.

2.6.16. Long term storage of radioactive waste involves a period of time (usually between 50 and 100 years) that will exceed the normal design lifetime of civil structures, including those used in short term storage facilities. This aspect have to be considered in the selection of materials, operating methods, quality assurance and quality control requirements. Specific issues that should be given special consideration in the safety assessment for long term storage of radioactive waste include the time frame for the assessment of the storage facility, the importance of passive safety features, retrievability, and the management system. An ageing management programme should be established to deal with ageing related degradation and this program should include provisions for the monitoring necessary for early detection of any deficiency. A plan for safe handling of the radioactive waste following long term storage should also be considered in the safety assessment and the potential effects of degradation of waste packages on the ability to retrieve and handle the radioactive waste should be assessed.

2.6.17. If the safety assessment results do not demonstrate compliance with the safety requirements or criteria, the assessment should be revised. The results of the revised assessment should be used to propose amendments to the existing safety case, or to identify activities, engineering and protective safety measures, and, where appropriate, additional safety measures to ensure compliance with the safety requirements and criteria.

2.7. Independent verification of safety assessment results

2.7.1. The operator should ensure the independent verification of the safety assessment through a formally documented examination of the results by a suitably qualified expert or group of experts who have not been directly involved in the development of the safety assessment and have no direct interest in the outcome of the work. Each independent verification should be fully documented, including the scope and terms of reference for the review, the basis for selection of reviewers, the findings of the peer review, the answers of the assessment authors to peer review comments and reviewers' evaluations of the responses. The independent verification report should be included in the safety case.

2.8. Review and modification of the safety assessment, iteration

2.8.1. During the site selection, certain assumptions will have to be made regarding the design and the potential location of the facility and, thus, the safety assessment in this stage could provide only a preliminary estimation of the safety of the facility. This will be acceptable if the safety assessment will determine that the proposed site is, in principle, suitable for a predisposal waste management facility. At later stages, when details of the proposed design will be defined, operational aspects will have to be addressed in more details. Throughout this process, the safety assessment prepared for each stage of the process should provide sufficient confidence to support the decisions required for the licensing of the facility.

2.8.2. In accordance with the graded approach, the extent and complexity of the safety assessment will vary with the facility/activity type and should be commensurate with the magnitude of the associated hazards. The complexity of the safety assessment performed at the different stages of the development of a facility will also vary, depending on the stage and the availability of the required data.

2.8.3. The level of detail to which the safety assessment models are developed and the associated amount of data required will depend on the assessment context but also on the stage of iteration of the assessment process. In early iterations (such as for site selection or in initial investigations), it might be sufficient to generate relatively simple models for screening purposes that can be implemented using simple computer tools such as spreadsheets and data that are readily available. Following the review of the results, it might be appropriate to collect further data and improve certain models and implement them using more sophisticated computer codes. Models and data for later iterations, especially for the final safety case, may need to be more comprehensive. Any lessons learned in applying the models and interpreting the results should be used to revisit the assumptions and the decisions made during the development of the model. Such information could be used to refine the model, e.g. by identifying particularly important processes or particularly sensitive parameters.

2.8.4. During the operational lifetime of the facility, there may be a need to modify some part(s) of the facility or some aspects of its operation. In case the modification could have an impact on safety, an appropriate safety assessment should be conducted or the current assessment should be revised, before implementation of the required change, in order to ensure that the established safety requirements will continue to be met. The results of the safety assessment should be compared with the safety case for operation and the approved documentation should be appended to the safety case.

2.8.5. The safety assessment for operation should be reviewed periodically in order to detect significant changes in the underlying assumptions, parameters and boundary conditions. If necessary, the safety case should be revised accordingly.

2.8.6. A periodic review of the safety assessment is also required in order to justify decisions to extend the life of the facility beyond its original design life, in case of a change of the ownership or management of the facility, or of the applicable regulations.

3. Safety Case

3.1. The safety assesment is required to be documented into a safety case, whit a content as defined in the Regulations on Notification and Authorisation of Practices involving Sources of Ionising Radiation. For the preparation of the safety case, the operator should take into consideration that the role of a safety case is:

a) to present all the safety arguments and supporting evidence that demonstrates the safety of the predisposal radioactive waste management facility or activity;
b) to provide the licensing documentation for the facility;
c) to integrate and present relevant scientific information in a structured, traceable and transparent way, demonstrating an understanding of the potential behavior and performance of the facility;
d) to demonstrate that all further steps in the management of the radioactive waste have been considered and in particular their compatibility, on both short term and long term;
e) to identify the uncertainties in the performance of the facility, describing the possible significance of these uncertainties, and identifying the approaches needed for the management of significant uncertainties;
f) to facilitate communication between interested parties on issues relating to the facility or activity.

3.1. Development of the safety case

3.1.1. The development of the safety case should commence at the begining of the process and should be continued throughout all of the steps in the development and operation of the facility, through to its decommissioning. The safety case should be used to guide the site selection, facility design, construction, operation and its decommissioning. It should also be used to identify research and development needs, and to identify and establish limits, controls and conditions at the various steps, and as a basis for the licensing process.

3.1.2. The development of the safety case is required to cover all the stages in the lifetime of the facility and, as such, is an iterative process that evolves with the development of the facility. The formality and level of technical detail of the safety case will depend on the stage of development of the facility and the decisions to be taken according to the national legislation. This approach should allow the identification of issues that require further attention in order to improve the understanding of aspects influencing the safety of the facility.

3.1.3. Predisposal radioactive waste management facilities are required to be developed in a step by step manner, which should enable:

a) the systematic collection, analysis and interpretation of the necessary scientific and technical data;
b) the evaluation of possible sites, radioactive waste management options, long term strategy and available technology;
c) the development of plans for design and operation;
d) iterative studies for design and safety assessment with progressively improving data;
e) the incorporation of comments from technical and regulatory reviews;
f) consultation with the public and other interested parties.

3.1.4. The step by step approach, together with the consideration of a range of options for the design and operation of a predisposal facility, should be such as to provide flexibility for considering new scientific or technical information and advances in radioactive waste management and materials technologies, as well as to social and economic aspects.

3.2. Use of the safety case

3.2.1. The safety case should demonstrate that there are adequate safety measures in place to meet the safety criteria, commensurate with the likelihood of occurrence of each event and the associated radiological consequences. Such measures may include:

a) engineered measures - technical or physical measures in place during operation, such as the provision of shielding;
b) procedural measures - in the event that engineered measures cannot fully eliminate a hazard, administrative measures may have to be used, such as restriction of access to areas with high levels of radiation.

3.2.2. The safety case should be used to assist in the establishment of licence conditions and other controls and requirements on the facility or activity. The specifications within which the facility can operate safely or the activity can be carried out safely should be identified, and the operational limits and conditions should be derived from the results of the safety assessment.

3.2.3. Specifications for safe operation should also be used as an input to the development of operational programmes and procedures, including maintenance, inspection and testing requirements.

3.2.4. Limits and conditions of particular importance for a predisposal facility are the acceptable waste inventory and/or the concentration levels for specific radionuclides in the waste. These should be defined on the basis of the results of the safety assessment. Waste acceptance criteria for the facility may be established both for individual waste packages and for the facility as a whole. In addition, the safety case should be used to assess the properties and levels of substances (e.g. chemicals) in the facility that may cause degradation of key safety features.

3.2.5. Each revision of the safety case should include a plan for further work as necessary to address remaining issues and, where possible, to reduce significant remaining uncertainties or to reduce their relevance or avoid them entirely by, for example, changes in the design of system components. At the earliest stages of development of a facility, there may be many open questions and uncertainties, and the safety case should include clear plans for dealing with these at future stages (e.g. by site characterization or by optimization of system design). Unresolved issues of high importance to safety should be given the highest priority for resolution. By the time the safety case is presented as part of a licence application, uncertainties and open questions with the potential to undermine safety should have been addressed in a manner appropriate for the decision to be taken.

3.3. Evolution of the Safety Case

3.3.1. During the development of a prediposal management facility, the safety case will evolve in five main steps:

a) Concept development and siting;
b) Design and construction;
c) Commissioning;
d) Operation;
e) Shutdown and decommissioning.

Concept development and siting

3.3.2. The first step in the pre-operational phase addresses concept development and design. The safety case for this step should present the strategy for safety and the way it will be met. Althouhg in this stage it will not be possible to provide a detailed description and assessment of the facility, key aspects relating to the strategy for safety and to the description of the design concept should be addressed. In addition, the approach to radiological impact assessment, the management system and management of uncertainties should be selected and justified, even though these aspects will evolve significantly in subsequent steps of the project.

3.3.3. The safety case in this stage should specifically address how the components of the facility will ensure implementation of all safety requirements. The safety case should include a description of the safety functions assigned to each component and should provide an assessment of the ability of these components to fulfil their given role. The safety case should explain how it is intended that the characteristics and properties of each component will meet their allocated safety functions and how this will evolve with time. This explanation should be supported by the following:

a) An overview of the technical feasibility of the proposed design options, identifying aspects that rely on already proven techniques and those that are new and need future confirmation through experimental tests;
b) An overview of the level of knowledge on the ability of each component to fulfil its expected role under anticipated conditions and disturbing events that have already been identified as possible perturbations;
c) An assessment of how the components will function together in a complementary manner to ensure that there is adequate defence in depth and that safety is not unduly dependent on a single safety function.

3.3.4. The radiological impact assessment can only be very preliminary at the stage of concept development. Nevertheless, such a preliminary assessment should be carried out in order to provide a broad estimate of the order of magnitude of possible impacts, on the basis of generic considerations of the performance of the site, and to begin to identify the features of the facility and environment that are likely to be important to safety.

3.3.5. One of the key aspects that have to be addressed at this stage is the siting of the facility. This should consider the effect the facility or activity will have on:

a) other activities at the site;
b) any neighbouring populations.

3.3.6. Consideration should also be given to:

a) the effect of other activities or facilities on the proposed facility;
b) the management of any secondary radioactive waste that will be generated by the facility operation or the activity, including the discharge or clearance of any radioactive material.

3.3.7. The safety case should also contain information about the management system of the future operator, such as the organizational structure and the resources necessary for the project, the programme for the project planning and the system that will be in place for the management of information. At this stage, arrangements for communication with the Agency and other interested parties, including the public, should be developed and put in place.

3.3.8. The aim of the safety case at this stage is to justify that construction of the facility can, in principle, be undertaken and that it appears safe to do so.

Design and construction

3.3.9. At the stage of design and construction, the safety case should be further developed, so that it can demonstrate that the following conditions are met:

a) the adopted design will meet all safety requirements;
b) the facility can be safely constructed.

3.3.10. The safety case should also demonstrate that the likelihood of a component failing is low and that, in the event of degradation, the loss of a safety function of one component will not jeopardize the safety of the whole system. Thus, the safety case should provide an assessment of the engineering aspects and of the impact of the facility or activity.

3.3.11. The aim of the safety case at this stage is to justify that the facility, as designed, can be safely constructed and operated.

Commissioning

3.3.12. In commissioning, specific attention should be paid to the performance of structures, systems and components important to safety. The safety case should demonstrate in this stage that the „as-built facility“meets the safety requirements specified in the final design. This should include the impact of any modifications to the design that might have been implemented during the construction period.

3.3.13. A commissioning schedule should be prepared, which should detail the tests to be undertaken and the expected results, to ensure that all aspects of the facility important to safety are adequately tested.

3.3.14. The safety case for commissioning should provide updated information about the management system of the operator, with particular emphasis on:

a) the organization and procedures that will be put in place to ensure the quality of the work performed;
b) the records keeping system;
c) design basis information, including information on design modifications;
d) the expertise available to carry out the commissioning tests and to operate the facility.

Operation

3.3.15. In the initial safety case for operation, evidence should be provided that the facility has been constructed in accordance with the design and that commissioning demonstrates that the facility can be operated safely. Information acquired during commissioning should be used to verify the validity of the safety assessment conducted for the previous stages, particularly regarding key assumptions and predictions. Any significant differences between the actual performance and predicted performance of the facility should be identified and the reasons for these differences should be investigated. All discrepancies should be justified. If there are safety implications, then a re-examination of the related structures, systems and components important to safety should be carried out.

3.3.16. The safety case for operation should provide updated information about the management system, with particular emphasis on:

a) the organization and procedures that are in place to ensure the safety of operations;
b) the record keeping and tracking system covering data, information and records of the decisions made;
c) the adequacy of the expertise available to operate the facility;
d) the interdependences.

3.3.17. Operations and events and occurrences in other comparable facilities should also be reviewed to identify any changes necessary before the facility is put into operation. The safety case should demonstrate that the as-built facility complies with the expectations of the operator and the Agency. The safety case should also provide evidence that the facility can be safely decommissioned.

3.3.18. The aim of the safety case at this stage is to justify the decision that the facility can be operated safely for a specific period of time and that it can then be safely decommissioned.

Shutdown and decommissioning

3.3.19. The shutdown and decommissioning of the facility has to be addressed from the earliest stage of the development of the safety case, to justify decisions on its safety. The justification should be based upon techniques that are currently available and should take into account the level of resources that are likely to be available at the time of shutdown.

3.3.20. A decommissioning plan is required to be developed since the early stages of the development of the facility, and this plan has to be periodically updated during the operation of the facility, up until its shutdown. The decommissioning operations will be conducted based on the final decommissioning plan, approved by the Agency, which should detail all the activities to be performed until the release of the site from the regulatory control.

3.3.21. The safety case for decommissioning should provide updated information about the management system, with particular emphasis on:

a) the organization and procedures that are in place to ensure the safety of decommissioning operations;
b) the record keeping and tracking system covering data, information and records of the decisions made;
c) the adequacy of the expertise available to decommission the facility;
d) the management of the radioactive waste that will be generated during decommissioning.

3.3.22. The aim of the safety case at this final stage is to demonstrate that the facility can be safely decommissioned and the the expected end state of the site will be reached according to the approved decommissioning plan.

4. Annex I

POSTULATED INITIATING EVENTS

A1. External natural PIE:

1. Extreme meteorological conditions:
   a) Strong winds, dust, sand storms (causing abrasive effects, damage to roofs or structures);
   b) Cyclones (causing damage and flying objects);
   c) Tornadoes;
   d) Hurricanes;
   e) Tsunamis;
   f) Lightning;
   g) Snow;
   h) Rain;
   i) Drought;
   j) Extreme temperatures (causing heating or freezing);
   k) Floods;
   l) Extremely high or low tides;
   m) Humidity and high salt content;
   n) Hail;
   o) Frost;
   p) Fog.
2. Seismic conditions;
3. Ground instability;
4. Landslides (e.g. due to ice melting);
5. Erosion;
6. Natural fires;
7. Volcanism;
8. Biological phenomena (e.g. algae or marine growth, fauna and flora invasion, and biological contamination).

A2. External human-induce PIE:

1. Explosions;
2. Fire from:
   a) The sea after oil spill from a vessel;
   b) Uncontrolled bush or veld fires.
3. Mining activities;
4. Projectiles, sources of high energy from machines and flying objects;
5. Aircraft crashes and other unpredicted mobile sources;
6. Sabotage;
7. Theft;
8. Nearby industrial activities (toxic gases, corrosion, smoke);
9. Transport infrastructure;
10. Nearby military activities;
11. Civil strife and war;

12. Electromagnetic interference (e.g. caused by a power station close by);
13. Floods due to dam failures.

B1. General internal PIE (generally applicable to most facilities and activities):

1. Loss of power;
2. Loss of ventilation;
3. Loss of containment;
4. Loss of confinement;
5. Loss of instrument control;
6. Lack of maintenance;
7. Failure of emergency equipment (e.g. malfunction of fire extinguishers);
8. Loss of utilities (e.g. cooling water, steam, compressed air).

B2. Internal PIE specific to storage facilities:

1. Accepting radioactive waste not in compliance with waste acceptance criteria;
2. Incorrect determination or no determination of chemical characteristics and other characteristics of radioactive waste in containers;
3. Loss of power;
4. Vehicle collision (e.g. fork-lift trucks damaging shielding, safety equipment or containers);
5. Loss or malfunction of instrumentation, which could result in loss of temperature control and failure of effective air monitoring;
6. Ineffective personal monitoring;
7. Faulty or ineffective security monitoring;
8. Faulty calibration instruments, leading to quality assurance and safety issues;
9. Malfunction of lifting equipment leading to falling or dropping of waste packages;
10. Loss of shielding (leading to overexposure of workers);
11. Criticality due to violation of storage arrangements;
12. Fire (due to, for example, sparks, cigarette smoking);
13. Improper inspection or inappropriate inspection frequency;
14. Failure of emergency equipment (e.g. malfunction of fire extinguishers);
15. Spontaneous combustion of materials;
16. Failure to control natural phenomena, such as a rising water table;
17. Loss of or insufficient ventilation, which could lead to internal contamination and surface contamination.

B3. Internal PIE specific to processing or conditioning facilities:

1. Insufficient or incorrect mixing between wastes and conditioning material;
2. Wrong classification or characterization of waste;
3. Chemical hazards present in waste to be processed (e.g. pH not neutralized prior to processing);
4. Wrong measurement of level or pressure, resulting in overfilling or overpressurizing of waste containers or equipment;
5. Wrong processing method applied (compressing material that is not compressible);
6. Incompatibility of process material and material of construction;

7. Addition of chemicals in wrong sequence, causing damage to equipment (e.g. through hot spots or corrosion);
8. Addition of wrong chemicals (leading to, for example, pH swing to wrong direction, wrong flux or chemical, ineffective decontamination, settling or separation);
9. Accumulation of fissile material in equipment (e.g. as sediment at bottom of tank, in evaporator), which could lead to criticality;
10. Incorrect setting on process control equipment;
11. Malfunction of instrumentation or equipment, leading to overfilling or underfilling of containers and/or inability to monitor;
12. Failure of process control equipment (e.g. heating, cooling, pressure control);
13. Wrong selection of waste (e.g. wrong identification of waste for packaging and waste for conditioning);
14. Wrong composition of raw material or solidification material, or wrong relation between mixing materials;
15. Internal missiles (e.g. from explosions, ruptures, collapses, dropping of loads, high energy rotating machinery);
16. Failure of safety systems, alarms and early warning systems;
17. Failure of emergency equipment (e.g. malfunction of fire extinguishers);
18. Fire;
19. Dust explosions;
20. Sparks from operating equipment;
21. Collision of transport vehicles (e.g. fork-lift trucks);
22. Failure of critical process equipment (e.g. liners in smelter);
23. Failure of equipment (e.g. overhead cranes) during handling of equipment;
24. Loss of water supply;
25. Ageing of equipment not properly monitored or managed;
26. Internal flooding due to pipe rupture, which could lead to criticality or other failure of equipment;
27. Voids in metal pipe to be melted leading to pressure buildup when melted, and then causing explosions.

B4. Internal PIE specific to long term storage facilities:

1. Waste accepted that is not in compliance with the facility was acceptance criteria;
2. Dropping or damage of waste containers during handling or loss of content, which could compromise the containment or shielding;
3. Waste containers not in compliance with requirements;
4. Loss of or compromise or deterioration of engineering controls;
5. Inspections being neglected;
6. Collapse or damage of structures (e.g. trenches) during offload of waste packages;
7. Leaking of waste containers;
8. Loss of shielding (e.g. damage to concrete drums during transport);
9. Effects due to natural weather conditions not managed (e.g. erosion after heavy rain);
10. Intrusion of animals, such as rabbits or rats, not controlled.

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