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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

AND

INTEGRATED REVIEW SERVICE FOR RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT, DECOMMISSIONING AND REMEDIATION (ARTEMIS)

COMBINED MISSION

TO

SPAIN

Madrid, Spain

14 to 26 October 2018

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY
and
DEPARTMENT OF NUCLEAR ENERGY

Integrated Regulatory Review Service
IRRS

ARTEMIS
Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation


CSN
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SEGURIDAD NUCLEAR


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DE ESPAÑA
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PARA LA TRANSICIÓN ECOLÓGICA


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GOBIERNO
DE ESPAÑA
MINISTERIO
DE ASUNTOS EXTERIORES, UNIÓN EUROPEA
Y COOPERACIÓN

IAEA Integrated Regulatory Review Service IRRS

ARTEMIS
Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation

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IAEA IRRS

ARTEMIS
Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation

REPORT OF THE

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION

INTEGRATED REVIEW SERVICE FOR RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT, DECOMMISSIONING AND REMEDIATION (ARTEMIS)

COMBINED MISSION

TO

SPAIN

Mission dates:	*14-26 October 2018*
Organizations visited:	*Consejo de Seguridad Nuclear/Nuclear Safety Council (CSN)* *Ministerio para la Transición Ecológica / Ministry for the Ecological Transition (MITECO)* *Empresa Nacional de Residuos Radiactivos (ENRESA)*
Location:	*Madrid, SPAIN*
Regulated facilities, activities and exposure situations in the scope of the IRRS component of the combined mission:	*Nuclear power plants, fuel cycle facilities, waste management facilities, radiation sources in industrial and medical facilities, NORM facilities and activities, emergency preparedness and response, transport, decommissioning, control of medical exposure, occupational exposure control, environmental monitoring, control of discharge and public exposure*
Radioactive waste and spent nuclear fuel management, decommissioning and remediation areas in the scope of the ARTEMIS component of the combined mission	*National policy and framework for radioactive waste and spent fuel management; national strategy for radioactive waste and spent fuel management; inventory of spent fuel and radioactive waste; concepts, plans and technical solutions for spent fuel and radioactive waste management; safety case and safety assessment of radioactive waste and spent fuel management activities and facilities; cost estimates and financing of radioactive waste and spent fuel management; capacity building for radioactive waste and spent fuel management – expertise, training and skills*
Organized by:	*International Atomic Energy Agency (IAEA)*

IRRS REVIEW TEAM

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LAREYNIE Olivier	Reviewer (France)
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MORRIS Scott	Reviewer (United States of America)
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ARTEMIS REVIEW TEAM

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BRUNO Gérard	ARTEMIS Team Coordinator (IAEA)
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IAEA-2018

The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS/ARTEMIS reports from different countries should not be attempted.

EXECUTIVE SUMMARY

Context

The IRRS-ARTEMIS Combined Team (the Team) appreciated the recognition by the Spanish authorities of the preeminent importance of nuclear and radiation safety, and that it is about more than just applying technical or engineering standards. It is also crucially dependent on those who work in the organizations that control the technology – people in the operating organizations, the regulatory body, as well as the government. Thus, safety relies on people who must exhibit a challenging and questioning attitude, a never-ending quest for improvement, and an unrelenting focus on radiation and nuclear safety. In other words, safety requires a strong commitment to an effective safety culture. This is particularly important for the leaders of the organizations responsible for ensuring safety, if excellence is to be achieved.

As an indication, reviewers from the Team who visited the Vandellos II nuclear power plant and the Juzbado Nuclear Fuel Fabrication Facility to witness regulatory inspectors' work reported very favourably on the observed standards of safety and operational excellence. This is consistent with the recent IAEA Operational Safety Review Team (OSART) service at a nuclear power plant in Spain. These outcomes reflect well on the Spanish nuclear regulatory system as well as the commitment, investment, leadership, and management of the operating organizations.

This report, in particular its recommendations and suggestions, should be viewed in this context. In inviting the IAEA to conduct this unique mission, the Spanish government has demonstrated its commitment to a basic principle for excellence in nuclear and radiation safety – a quest for continuous improvement.

Scope

At the request of the Spanish authorities, an international Team of 24 senior nuclear safety and radiation safety experts and 8 IAEA staff met with representatives of the Nuclear Safety Council (CSN), the Ministry for the Ecological Transition (MITECO), and the Spanish Radioactive Waste Management Agency (ENRESA) from 15 – 26 October 2018 to conduct a combined Integrated Regulatory Review Service (IRRS) and Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation (ARTEMIS) mission. The purpose of the combined IRRS-ARTEMIS mission was to perform a peer review of the infrastructure for safety in Spain on matters of nuclear safety, radiation protection, and management of spent fuel and radioactive waste. This first-of-a-kind mission combining two peer review services, the IRRS and ARTEMIS components, was intended to promote efficiency in the allocation of peer review resources and exploit synergies between the respective reviews.

The IRRS component of the peer review provided an independent expert assessment of the Spanish regulatory framework, functions and activities, assessed the effectiveness of their application and exchanged information and experiences in the areas covered by the IRRS. The IAEA safety standards served as the basis for the IRRS review. The scope of the IRRS review included all of the national organizations in Spain that legally and collectively provide the full scope of the national regulatory responsibilities and functions subject to the review. The review included all modules except the interfaces with nuclear security and uranium mines.

The ARTEMIS component of the peer review provided independent expert opinion and advice on radioactive waste and spent nuclear fuel management, based upon the IAEA safety standards and technical guidance, as well as international good practices.

In addition, a full-scope combined IRRS-ARTEMIS mission includes a review of the control of medical exposure to ionizing radiation, including the consideration of public, occupational, patient and environmental protection. However, during the planning and preparation phase for the mission to Spain, the IAEA did not ensure fulsome development of the necessary arrangements with the Autonomous

Communities responsible for patient protection. As a result, although the Team met with representatives from the Ministry of Health and addressed legal framework and policy matters for patient protection, it was unable to assess the implementation of the associated regulations. With the full support of the Spanish Authorities, the IAEA has committed to include the Autonomous Communities responsible for patient protection in a future mission to Spain.

IRRS-ARTEMIS Methodology

The combined IRRS-ARTEMIS mission addressed regulatory, technical and policy issues. The relevant regulatory areas of the IRRS component included: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; activities and functions of the regulatory body, including the authorization process, review and assessment, inspection and enforcement, the development of regulations and guides; emergency preparedness; and the management system. At the request of CSN, the IRRS component also included a discussion during which members of the Team shared views from their respective regulatory bodies regarding two policy issues, Financial Independence and Human Resources:

- Regarding Financial Independence, each Team member noted that, while operating within their national fiscal system and budgetary constraints, their respective regulatory bodies have considerable freedom to allocate resources to suit their needs. In addition, the Team members stated that their regulatory bodies have the authority to make changes to their organizational structure without the need for external approval, including organizational changes to optimize the efficiency and effectiveness of safety decision-making.
- With respect to Human Resources, each Team member indicated that their respective regulatory bodies have both the authority and flexibility to recruit as needed, and as enabled by the available budget. In addition, Team members noted that their organizations implement a training and development programme based on a systematic analysis of essential competence and skills needs and includes the identification and delivery of specific required training.

The topics reviewed by the ARTEMIS component for radioactive waste and spent fuel management included: the national policy, framework and strategy; the inventory, concepts, plans and technical solutions; the safety case and safety assessment; and the cost estimates, financing, and capacity building.

The combined mission included a series of interviews and discussions with key personnel at the CSN, the Ministry for the Ecological Transition, ENRESA, and the Ministry of Health. It also included Team member observations of inspections conducted by the regulator at various facilities, including the Vandellós II nuclear power plant, the Juzbado Nuclear Fuel Fabrication Facility, and at CGS Tecnos, S.A., a large industrial radiography facility. Senior members of the Team also met with the Secretary of State for Energy and with the CSN Board to discuss the combined mission as well as other regulatory matters of mutual interest.

Results

The Spanish authorities supplied substantial documentation to support the Combined IRRS-ARTEMIS mission, including the results of detailed self-assessments with an evaluation of the strengths and proposed actions for further improvement. The Team was positively impressed by the extensive preparation, expertise and dedication of the staff from the Ministry for the Ecological Transition, the Ministry of Health, CSN, and ENRESA. Throughout the review, the administrative and logistical support was outstanding. In addition, the Team was extended full cooperation in technical, regulatory, and policy discussions with the management and staff of the Spanish authorities.

The Team identified a Good Practice for CSN in the area of Transportation Safety, finding that the observed management system tool can make a significant contribution to nuclear and radiation safety, and should be promoted at an international level. The Team also identified a number of areas of good performance

evidenced by the policies, the regulatory framework, as well as the regulatory and operational activities implemented by the Spanish authorities, including:

- The delivery of comprehensive, user-friendly content on the CSN website containing information on public and environmental radiation exposure;
- Participation in international outreach and cooperative engagements by CSN in the areas of nuclear and radiation safety to strengthen the global safety regime;
- The CSN requirement for nuclear power plants to conduct safety culture self-assessments annually and the associated biannual regulatory inspections of safety culture;
- The comprehensive assessment of lessons learned and stress tests in response to the accident at the Fukushima Daiichi Nuclear Power Plant, the timely application of associated changes to the Spanish regulatory system, as well as the implementation of safety improvements at Spanish nuclear power plants and facilities;
- The delivery of comprehensive, inter-linked instructions and guides to support users in the correct application of regulations governing the transport of radioactive material;
- Arrangements for alternative emergency operations backup facilities and support agreements with CSN and other organizations to strengthen radiological response capabilities.

The Team also observed that Spain has developed a strategy to describe the safe management of current and future radioactive waste and spent fuel generated in the country, including waste from the decommissioning of existing facilities. The Team considers that the proposed strategy is commendable and consistent with international safety standards.

In the spirit of continuous improvement, the Team report includes a number of recommendations and suggestions to improve the Spanish nuclear regulatory infrastructure and regulatory practices on matters of nuclear and radiation safety. Many of the recommendations and suggestions address areas in which the Spanish authorities previously identified opportunities to improve and had already initiated programme changes. The Team concluded that the following issues are representative of those which, if addressed by the Government of Spain, the Regulatory Authorities[1] should further enhance the overall effectiveness of the regulatory system:

The Government:

- take immediate steps towards making decisions regarding updates to the General Radioactive Waste Plan (GRWP);
- establish mechanisms to ensure the effective implementation of the responsibilities assigned to the Competent Autonomous Community Health Authorities;
- ensure that a national radon action plan is completed and implemented;
- establish reference levels for public dose exposure due to radionuclides in construction materials;
- enhance provisions to ensure coordination among operating organizations, as well as response organizations and the regulatory authorities, during a nuclear and radiological emergency;
- propose the revision of the regulatory framework to strengthen the control over radioactive facilities and related activities;
- update the dose limits for the lens of the eyes to comply with the applicable standards;

[1] Regulatory Authorities comprise: CSN, Ministry for the Ecological Transition; Ministry of Foreign Affairs; European Union and Cooperation; Ministry of Health; Consume and Social Welfare; Ministry of Civil Works Ministry of Home Affairs; Autonomous Communities

The Regulatory Authorities:

- enhance the process for establishing and amending regulations and guides to include regular and systematic reviews;
- conduct a comprehensive review of regulatory provisions to ensure consistency with applicable safety standards; and,
- require the relevant authorized parties to inform the public about the possible radiation risks associated with their facilities and activities.

CSN:

- complete cooperation agreements with other competent authorities regarding the management of contaminated sites;
- develop and implement provisions to conduct regular self-assessments of its management system;
- develop a consolidated and comprehensive set of emergency preparedness and response regulatory provisions;
- consider engaging in a discussion with the government, to obtain the flexibility to adjust its organizational structure; and,
- consider enhancing its training activities by establishing a more systematic approach to training and by considering formal qualification for certain positions.

In addition, the Team observed that the delay in the Spanish decision regarding long term operation of nuclear power plants creates uncertainty in the resourcing and staffing decisions of the regulatory body. While appreciating the overarching national importance of this decision, the consequences for CSN include a potential imbalance in projected regulatory workload as well as the available competent human resources. This imbalance could lead to inefficiencies and delays, particularly in the execution of periodic safety reviews, and other licensing and safety oversight activities. However, with the aim of continuous improvement in the conduct of nuclear safety regulation, the Team hopes that the issuance of a timely decision on long term nuclear power plant operation in Spain will better inform the critical resource decision making and workload management projections within CSN.

The Team identified a Good Practice for ENRESA in the design of the Centralized Storage Facility. The design and its use as part of the strategy to manage spent fuel in Spain, could make a significant contribution to nuclear and radiation safety and should be promoted internationally. In addition, in the spirit of continuous improvement, the Team also made a number of recommendations and suggestions to improve the Spanish nuclear regulatory and operational practices for spent fuel and radioactive waste management. As with the IRRS component, many of the recommendations and suggestions relate to areas in which the Spanish authorities previously identified opportunities to improve.

The Team also observed that Spain has developed a strategy to describe the safe management of current and future radioactive waste and spent fuel generated in the country, including waste from the decommissioning of existing facilities. The strategy indicates that the final destination for all types of radioactive waste and spent fuel is safe disposal in appropriate facilities. In this respect, Low and Intermediate Level Waste (LILW) is currently successfully disposed of in the El Cabril Disposal Facility, which includes capacity for the disposal of Very Low-Level Waste (VLLW) in dedicated vaults.

In addition, a Deep Geological Disposal (DGD) facility is planned for higher level radioactive waste and spent fuel. Individual dry storage facilities have been built at most reactor sites to allow for the management of spent fuel and the strategy includes the creation of a Centralized Storage Facility (CSF). The CSF, which has been designed using international best practices, would provide for the necessary flexibility to ensure the continuity of waste and spent fuel management in the case of events that would result in the unavailability of onsite storage capacity at reactor sites, and for undertaking research on fuel behaviour in preparation for deep geological disposal.

However, the review team found that the development and refinement of the radioactive waste management (RWM) strategy has been delayed, raising concerns regarding the sustainability of the strategy as well as the durability of the necessary support for its implementation. This is based on the following observations:

- the General Radioactive Waste Plan (GRWP) has not been officially revised and endorsed since 2006, although ENRESA has completed several GRWP updates, including actions to further develop the DGD facility;
- the development of the CSF, which is considered a high priority for the safe and successful execution of Spain's RWM strategy, has experienced delays, including the decision by the government to temporarily suspend the CSF licensing process; and
- the tax rates considered in the funding mechanism for the implementation of the RWM strategy have not been updated since 2010.

These observations prompted the Team to identify findings to further stimulate the implementation of the RWM strategy in Spain. The following areas are representative of some of the recommendations and suggestions included in the ARTEMIS component of the report:

- Update to the GRWP – making decisions regarding updates to the GRWP would contribute to the continued safe and sustainable management of radioactive waste;
- Delay in Establishment of CSF - further delays in the establishment of the CSF could adversely impact the management of spent fuel and high-level waste;
- DGD Facility Development - action by the Government, CSN and ENRESA to develop regulations, an implementation plan, and technical requirements for the development of the DGD facility would better enable Spain to meet key milestones and deadlines in the national plan;
- RWM Strategy Funding – routine review and update of the RWM funding mechanism would help to ensure the successful implementation of the strategy; and,
- DGD Facility Research & Development (R&D) Programme Support – sufficient R&D funding and knowledge management efforts would help to maintain and improve the competences needed to support the implementation of the DGD programme.

In light of the ongoing and future challenges in the nuclear industry in Spain, including those associated with the implementation of the radioactive waste management plan, the decision making for the long-term operation of nuclear power plants as well as the licensing and development of the CSF, the Team believes the mission to Spain was timely. The Team also believes the recommendations and suggestions, if acted upon, will contribute to the continued improvement of nuclear and radiation safety, including the safe management of spent fuel and radioactive waste in Spain.

In closing, in the spring of 1963, Dr. Martin Luther King, Jr., penned a letter from the Birmingham (Alabama, USA) jail, in which he referred to "an inescapable network of mutuality." Given our common commitment to the importance of nuclear and radiation safety the Team considers our counterparts in Spain to be members of our common inescapable network of mutuality for ensuring safety. To that end, the Team received the full cooperation of our counterparts in an open, transparent and collegial manner throughout the mission. This openness contributed to the strong consensus among the members of the Team that they gained a number of useful insights from this unique mission, contributing to their respective regulatory experience and safety perspective.

An IAEA press release was issued at the end of the mission and a press conference was organized.

INTRODUCTION

At the request of the Government of Spain, an international team of senior safety experts met representatives of Consejo de Seguridad Nuclear (CSN), the regulatory body of Spain, representatives of Ministry for the Ecological Transition (MITECO), and representatives of Spanish Radioactive Waste Management Agency (ENRESA) from 15 to 26 October 2018, to conduct the first Integrated Regulatory Review Service (IRRS) and Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation (ARTEMIS) combined mission.

The purpose of this combined peer review was to review the Spanish regulatory framework for nuclear and radiation safety (IRRS) and to provide independent experts opinion and advice on radioactive waste and spent nuclear fuel management, decommissioning and remediation (ARTEMIS).

The combined mission was formally requested by the Government of Spain in June 2016. A preparatory mission was conducted 25-26 January 2018 at CSN Headquarters in Madrid to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities, and exposure situations in Spain and their related safety aspects as well as the Spanish Policy and Strategy on Spent Fuel and Radioactive Waste Management, in order to agree the scope of the combined IRRS - ARTEMIS mission.

The IRRS - ARTEMIS combined review team consisted of 24 senior experts from 16 IAEA Member States, 6 IAEA staff members and 2 IAEA administrative assistants, and 4 observers.

The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response. In addition, policy issues were discussed, including: financial independence and human resources.

The ARTEMIS team reviewed the following areas: national policy and framework for radioactive waste and spent fuel management; national strategy for radioactive waste and spent fuel management; inventory of spent fuel and radioactive waste; concepts, plans and technical solutions for spent fuel and radioactive waste management; safety case and safety assessment of radioactive waste and spent fuel management activities and facilities; cost estimates and financing of radioactive waste and spent fuel management; capacity building for radioactive waste and spent fuel management – expertise, training and skills.

Spain conducted self-assessments in preparation for the IRRS -ARTEMIS combined mission. The results of Spain self-assessments and supporting documentation were provided to the review team as advance reference material for the mission. During the combined mission the review teams performed a systematic review of all topics within the agreed scope through review of Spain advance reference material, and conducted interviews with management and staff from CSN, MITECO and ENRESA. Direct observations of CSN regulatory activities at regulated facilities were also conducted.

Meetings with the Secretary of State of Energy and with the CSN Board were also organized.

All through the combined mission the review teams received excellent support and cooperation from CSN, MITECO and ENRESA.

CONTENTS – IRRS (COMPONENT I)

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ARTEMIS (COMPONENT II)

I. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Spain radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Spain with the exception of the security and uranium mines.

A full-scope mission includes a review of the control of medical exposure to ionizing radiation, including the consideration of public, occupational, patient and environmental protection. However, during the planning and preparation phase for the mission to Spain, the IAEA did not ensure fulsome development of the necessary arrangements with the Autonomous Communities responsible for patient protection. As a result, although the Team met with representatives from the Ministry of Health and addressed legal framework and policy matters for patient protection, it was unable to assess the implementation of the associated regulations. With the full support of the Spanish Authorities, the IAEA has committed to include the Autonomous Communities responsible for patient protection in a future mission to Spain.

It is expected this IRRS mission will facilitate regulatory improvements in Spain and other Member States, utilising the knowledge gained and experiences shared between CSN and IRRS reviewers and the evaluation of the Spanish regulatory framework for nuclear safety, including its good practices.

The key objectives of this mission were to enhance the national legal, governmental and regulatory framework for nuclear and radiation safety, and national arrangements for emergency preparedness and response through:

- providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
- providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- promoting the sharing of experience and exchange of lessons learned among senior regulators;
- providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Review Team members who have experience of other regulatory practices in the same field;
- providing the host country with recommendations and suggestions for improvement;
- providing other states with information regarding good practices identified in the course of the review;
- providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);
- contributing to the harmonization of regulatory approaches among states;
- promoting the application of IAEA Safety Requirements;
- providing feedback on the use and application of IAEA safety standards

II. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Spain, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) and Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation (ARTEMIS) combined Mission was conducted from 25 to 26 January 2018. The preparatory meeting was carried out by the appointed Team Leader Mr Victor McCree, Deputy Team Leader for IRRS Mr Carl-Magnus Larsson, Francois Besnus, Deputy Team Leader for ARTEMIS and the IRRS IAEA Team representatives, Mr David Senior, Section Head, Mr Jean-René Jubin Team Coordinator for IRRS, Mr Gerard Bruno Team Coordinator for ARTEMIS, Mr Ronald Jimenez Pacheco Deputy Team coordinator for IRRS, and Mr Clement Hill Deputy Team coordinator for ARTEMIS.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of Spain represented by Mr. Fernando Marti Scharfhausen, President of the Consejo de Seguridad Nuclear (CSN), Commissioners, and other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Nuclear power plants;
- Fuel cycle facilities;
- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Waste management (policy and strategy, predisposal and disposal); and
- Selected policy issues.

Spanish representatives from CSN, Ministry of Foreign Affairs and Cooperation (MAEC), Ministry of Energy, Tourism and Digital Agenda (MINETAD) and Spanish Radioactive Waste Management Agency (ENRESA) made a presentation describing the current Framework for Safety in Spain and the activities related to radioactive Waste Management as well as the self-assessment results to date.

CSN Commissioners Mr. Javier Dies, Mr Manuel Rodriguez, General Secretary of CSN, Mr Antonio Munuera, Technical Director on Nuclear Safety and Mrs Maria Fernanda Sanchez, Technical Director on Radiation Protection, made presentations on the national context, the current status of Spain and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the work plan for the execution of the IRRS mission in Spain in October 2018.

The proposed composition of the IRRS Review team was discussed and tentatively confirmed. Logistics including meeting and work places, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The Spanish Liaison Officers for the IRRS mission were confirmed as Ms Fernanda Sanchez and Mr Antonio Munuera.

Spain provided IAEA with the advance reference material (ARM) for the review at the end of July 2018.

In preparation for the mission, the IAEA review team members reviewed the Spain ARM and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VIII.

C) CONDUCT OF THE REVIEW

The initial IRRS Review team meeting took place on Sunday, 14 October 2018 in Madrid, Spain, directed by the IRRS Team Leader. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced during a refresher training course. The agenda for the mission was presented to the IRRS team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officers were present at the initial IRRS Review team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The entrance meeting was held on Monday, 15 October 2018, with the participation of CSN senior management and staff. Opening remarks were made by Mr. Fernando Marti Scharfhausen, President of the Consejo de Seguridad Nuclear (CSN), Mr Victor McCree, IRRS Team Leader and Mr David Senior IAEA Representative. Ms Fernanda Sanchez and Mr Antonio Munuera gave an overview of the Spanish context, CSN activities and the action plan prepared as a result of the pre-mission self-assessment. The Team Coordinators of the IRRS - ARTEMIS Combined mission presented the arrangements in place to ensure and effective coordination between both IRRS and ARTEMIS Teams.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Spain and CSN with recommendations and suggestions for improvement and where appropriate, identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

The IRRS Review team performed its review according to the mission programme given in Appendix II.

Following a written approach from a CSN trade union representative to the IRRS team, CSN facilitated a meeting between the IRRS team and representatives of five trade unions. The CSN response to the request was welcomed by the IRRS team and maintained the overall inclusive and transparent conduct of the mission. Together with the IRRS team's interactions with the CSN Board and with counterparts, the discussions with the trade unions helped inform the IRRS Team of a range of matters linked mainly to Module 3 (Responsibilities and Functions of the Regulatory Body). To the extent the information fell within the scope of the mission, it contributed to the conclusions recorded in this report.

The exit meeting was held on Friday, 26 October 2018. The opening remarks at the exit meeting were presented by Mr. Fernando Marti Scharfhausen, President of CSN and were followed by the presentation of the results of the mission by the IRRS team Leader Mr Victor McCree. Closing remarks were made by Mr Greg Rzentkowski, Director, Division of Nuclear Installation Safety, IAEA.

A joint IAEA and CSN/ENRESA press conference took place at the end of the combined mission. An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Spanish national policy and strategy for safety is embedded in several instruments including the Law 25/1964, of April 29, on Nuclear Energy (Nuclear Energy Law) which:

1) Establish the legal regime for the development and implementation of the peaceful application of nuclear energy and ionizing radiation in Spain, in order to adequately protect people, things, and the environment.
2) Regulate the implementation of the international commitments made by the State in the field of nuclear energy and ionizing radiation."

Additionally, Spain has developed the necessary legislative and regulatory framework for the protection of people and the environment against the harmful effects of the use of nuclear energy and ionizing radiation. This legislative and regulatory framework includes, among others:

- Law 15/1980, of April 22, creating the Nuclear Safety Council (CSN) (CSN Creation Law)
- Royal Decree 1836/1999, of December 3, approving the regulation on nuclear and radioactive facilities (Royal Decree 1836/1999)
- Royal Decree 783/2001, of July 6, approving the regulation on sanitary protection against ionizing radiations (Royal Decree 783/2001)
- Royal Decree 102/2014, of February 21, for the responsible and safe management of spent fuel and radioactive waste (Royal Decree 102/2014)
- Royal Decree 1085/2009, of July 3, approving the regulation on installation and use of X-ray apparatus for medical diagnosis (Royal Decree 1085/2009)
- Royal Decree 1546/2004, of June 25, approving the basic nuclear emergency plan (Royal Decree 1546/2004)
- Royal Decree 1440/2010, of November 5, approving the statute of CSN (Royal Decree 1440/2010)

Graded approach is embedded in the Royal Decrees in different ways:

- The inherent risks associated to each facility are taken into account in the authorization system under Royal Decree 1836/1999, e.g., categorization of nuclear facilities and radioactive facilities
- The implementation of measures for the safe management of spent fuel and radioactive waste follow a graded approach, so that the detail of assessment and documentation are proportionate to the magnitude of risk involved under Royal Decree 102/2014.

The national policy and strategy, as supplemented by CSN instructions and guides, takes into account important factors such as the IAEA Fundamental Safety Principles, adequate mechanisms for considering social and economic developments, and promotion of leadership and management for safety.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Spanish legislative and regulatory framework for nuclear safety and radiation protection is based on the following legal documents.

Laws forms bases for regulations, authorization, inspection and enforcement. Laws are approved by the Parliament.

Royal Decrees and Rules are requirements and procedures to implement the Laws. Royal Decrees are issued by the Government and do not need to be approved by the Parliament.

CSN Instructions are technical standards on nuclear safety and radiological protection issues. Instructions are issued by CSN and are mandatory.

CSN issues Complementary Technical Instructions (ITC) to license holders, whose implementation is mandatory.

Circulars and Guides provide guidance to meet the regulatory requirements. They are issued by CSN.

In the area of nuclear safety, the following two laws provide the basis of legal framework:

- Nuclear Energy Law (25/1964), which is the basic law establishing the general concepts and principles governing peaceful use of nuclear energy
- CSN Creation Law (15/1980), which creates the CSN as the sole competent body on nuclear safety and radiation protection

The important Royal Decrees in the area of nuclear and radiological safety and emergency response are:

- Royal Decree 1836/1999, which stipulate the procedure and requirements for nuclear and radioactive facilities
- Royal Decree 783/2001, which stipulates the procedure and requirements for radiation protection
- Royal Decree 1085/2009, which stipulates on installation and use of X-ray apparatus for medical diagnosis
- Royal Decree 229/2006, which stipulates on the control of high activity sealed radioactive sources and orphan sources
- Royal Decree 102/2014, which stipulates the responsibility for safe management of spent fuel and radioactive waste
- Royal Decree 1546/2004, which stipulates on basic Nuclear Emergency Plan

The CSN proposed the Government to issue a Royal Decree on nuclear safety criteria, which transposes Directive 2014/87/EURATOM, following public consultation and the subsequent CSN board decision in May 2018. This draft Royal Decree is currently under inter-ministerial coordination. The CSN also proposed the amendment of Royal Decree on regulation on nuclear and radioactive facilities, and Royal Decree on regulation on Sanitary Protection. The CSN informed important elements in Directive 2014/87/EURATOM, which is reflected as lessons learned from Fukushima Dai-ichi Accident, to the licensees through Complementary Technical Instructions.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The CSN is the sole competent body on nuclear safety and radiation protection matters in Spain, and its functions are defined in Article 2 of CSN Creation Law. The Ministry for the Ecological Transition (MITECO) has the responsibility to issue licenses associated with nuclear and Category 1 radioactive facilities, and transport. The Governments of Autonomous Communities with responsibilities transferred in this area, issue licenses associated with Category 2 and 3 radioactive facilities as well as registrations of practices involving X-ray devices used in medicine.

Independence of CSN

The CSN Creation Law states that CSN is independent from the General State Administration. That Law also states that its assets and legal status are independent from those of the State and CSN is a competent regulatory body for nuclear safety and radiation protection.

The Chairman and Commissioners of CSN shall be appointed by the Government, with the process of the agreement by the Congress, based on the proposal of MITECO, in accordance with the defined requirements and conditions. Chairman and Commissioners shall resign when they reach the age of 70, complete their

mandate, at their own request, or following a decision of the Government with the same procedures established for their nomination.

The CSN recruits the staff under the annual national offer of public employments, which is applicable to all public entities. In its recruiting process, CSN is allowed to recruit the staff belonging to the A1 Category (University graduate) and implements its own selection tests.

During a recent episode of fiscal austerity and associated constraints imposed on staffing levels across the Public Civil Service, CSN had to seek an exemption from restrictions on recruitment despite the fact that the utilities continued to pay fees as prescribed in Law 14/1999, of May 4, governing public prices and fees for services rendered by the CSN (Law 14/1999). The CSN was successful in obtaining an exemption, and the IRRS team was provided assurances that CSN has maintained a staffing level that can sustain CSN's statutory functions; for example, 25 recruitments were approved for 2018, commensurate with the rate of attrition in the three coming years (mainly through retirement). While the ability of CSN to deliver on its statutory obligations was thus unharmed, the IRRS team considers that the staffing level should first and foremost be commensurate with the resources expended on regulatory efforts, the objective of ensuring safe operations of all regulated facilities and activities, and the fees paid by the regulated entities; "for the performance of services and of activities by the Nuclear Safety Council" (Law 14/1999).

The IRRS team finds that CSN Statute defines organizational structure in detail, and it may limit the flexibility in adjusting its organisational structure to the changes in circumstances (See 3.1) It also finds that the rule for State budget applicable to all the public entities also restricts some of the CSN activities, e.g. participation to international activities to continue fulfilling its international obligation. The CSN submits an annual report on its activities to the Parliament.

Role and Responsibility of CSN in regulatory framework

The CSN is empowered as regulatory body for nuclear safety and radiation protection as in the followings, based on CSN Creation Law, Nuclear Energy Law and the relevant Royal Decrees:

Guides and Regulations: CSN can draft and issue Instructions, which are binding, through public consultation, but consultation with MITECO is not required. The Instructions are published in the Official State Gazette and informed to Parliament and European Commission. The CSN also issues Circulars and Guides (non-binding).

CSN can propose the establishment and modification of Law and Royal Decree to the Government, through MITECO, as stipulated in Royal Decree 864/2018, of July 13, on MITECO organizational structure (Royal Decree 864/2018). The CSN informed the IRRS team that MITECO respects CSN proposal in terms of nuclear safety and radiation protection and does not change the content.

Licenses: The CSN issues the report on assessing licensing applications, and that report is mandatory in all the cases as well as binding to the MITECO and Autonomous Communities, e.g., the licenses are denied when the report is negative, the conditions and limits as written in that report are exactly attached to the licenses. However, when the report is positive, MITECO may include additional conditions (not related to nuclear safety nor radiological protection) in the authorization, or even deny it.

Inspections and Enforcement: The CSN can carry out all types of inspections during all stages and can terminate construction or propose the revocation of licenses when it finds major infringement for safety reasons. The CSN may propose the enforcement actions, e.g., sanctions, to MITECO and Autonomous Communities, with the report on evaluation of the infringement.

The IRRS team carefully reviewed the *de jure* and *de facto* independence of the CSN from MITECO, noting that MITECO is the regulatory authority to issue licensing and pose sanctions to licensees based on mandatory reports and proposals from the CSN. The IRRS team also notes that MITECO is assigned a role

to propose candidate of Chairman and Commissioners to the Government, and to bring the CSN's proposal of draft Royal Decrees, draft Laws, etc. to the Government.

The IRRS team finds that, based on CSN creation law, CSN has the *de jure* power to a) establish instructions, guides, etc., b) conduct review and assessments, c) conduct inspections and enforcement, and d) provide the mandatory report or proposal to competent authorities issuing licences or posing sanctions, for matters relating to nuclear safety and radiation protection. The IRRS team also finds that when CSN proposes regulations to the government MITECO does not change the proposal with regard to safety matters.

The IRRS team concludes that the CSN is able to make decision under its statutory obligation for the regulatory control of facilities and activities and to perform its functions without undue pressure or constraint.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In periods of fiscal austerity, CSN has had to negotiate exemptions from restrictions applied across the Civil Service and applied to, in particular, recruitment of new staff. This has occurred although the fees paid by the utilities have remained constant.*	
(1)	**BASIS: GSR Part 1 Requirement 3, states that** *"The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities."*
(2)	**BASIS: GSR Part 1 Requirement 4, para. 2.8 states that** *"To be effectively independent from undue influences on its decision making, the regulatory body:* *(a) Shall have sufficient authority and sufficient competent staff;* *(b) Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities;* *...* *(d) Shall be free from any pressures associated with political circumstances or economic conditions, or pressures from government departments, authorized parties or other organizations;*
S1	**Suggestion: The Government should consider making provisions to maintain the staffing level of CSN at the level necessary to achieve the safety objective and commensurate with the fees paid by the authorized parties.**

Policy Issue No. 1 - Financial independence

The discussion aimed at sharing and discussing experiences regarding the financial model and mechanisms used by different countries for ensuring regulatory bodies have access to sufficient financial resources for discharging effectively their statutory responsibilities.

CSN, independent regulatory body by Law 15/1980, is mainly funded by collecting fees from the authorized parties. This funding mechanism is a key element of its de jure independence. Nevertheless, the annual budget of CSN is part of the State General Budget and, therefore, subject to administrative expenditure

rules and audits. This administrative control may constraint the use of the allocated funds to the regulatory body, e.g., for travelling.

The funding provisions established in other countries vary from country to country. Some countries use similar provisions than Spain, i.e., based on a cost recovery approach which may be complemented by additional funding provided by the Government for activities not directly related to regulatory oversight of activities and facilities, such as those related to international cooperation and assistance. In other countries, the entire regulatory body's budget is allocated by the Government. In this case, usually the regulatory body submits a budget proposal, discussed at ministerial level, before being approved by Parliament.

In the vast majority of the cases, whatever the funding system, the budget of the regulatory body is subject to state administrative control usually through indicators and audits. However, most of the regulatory bodies, while acting within the fiscal system and budgetary constraints, has considerable freedom in allocation of resources to suit their needs and are able to adjust to new circumstances quickly through internal arrangements.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Nuclear Energy Law defines, in its Article 2, Title holder "as a natural or legal person, who is entirely responsible for a nuclear facility or radioactive facility, as specified in the corresponding authorisation. This responsibility cannot be delegated" That Law, with the amendment in 2007, further states: "Prime responsibility for safety is on the title holder and cannot be delegated."

The Royal Decree 1836/1999 stipulates in Article 12 that: the condition of title holder cannot be transferred without prior approval of the competent Ministry after the mandatory report of the CSN. The CSN proposed to include clear requirements in Article 5 of the Royal Decree on nuclear safety that will transpose Directive 2014/87/EURATOM: "Prime responsibility for safety is on the title holder and cannot be delegated" This Royal Decree is now under inter-ministerial coordination, pending of the Government approval.

That Royal Decree 1836/1999 stipulates in Article 8: "The licensee shall continuously strive to improve the nuclear safety and radiological conditions of his facility. In this respect he shall analyse technical improvements and existing practices, in accordance with the requirements established by the CSN, and implement those considered most adequate by the latter. CSN may at any time require the analysis of the licensee for the implementation of improvements to nuclear safety and radiological protection".

The Royal Decree states that a licensee is responsible for ensuring that contractors and sub-contractors comply with it. A licensee is required to have a quality assurance programme to assure contractors and sub-contractors comply with Article 8 of the Royal Decree.

1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

In the legal and regulatory framework of Spain, CSN is responsible for nuclear safety and radiation protection, while MITECO and Autonomous Communities are responsible for issuing authorization and enforcement measures based on the CSN mandatory reports (See 1.3).

MITECO is also responsible for Energy Policy and also a channel for CSN to communicate to the government, if necessary, e.g., about proposals of draft Royal Decrees or Law, annual budget, notification through diplomatic channel, as stipulated in Royal Decree (864/2018).

Regarding certain radioactive facilities, some inspections may be delegated to inspectors working for Autonomous Communities through service contracts. In that case, CSN accredits and provides training to local inspectors working on behalf of CSN.

The following authorities have responsibilities related to nuclear and radioactive facilities.

The Ministry of Health is responsible for radiation protection to patients, while CSN authorizes radiation protection services and supervises associated occupational exposure situation. The CSN signed a Memorandum of Understanding (MOU) with the Ministry of Health in 2010 for collaborations on several topics, in particular related with patient protection. However, this MOU has not been systematically implemented, although Article 2(h) of CSN Creation Act mandates CSN to collaborate with competent authorities in issues related with radiological protection of the people subject to medical diagnosis or treatment procedures with ionising radiation. This issue was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

Responsibilities for radiological protection of the patient has been assigned to the Autonomous Communities, by Law 14/1986 on "General Health", the Laws that establish each Autonomous Community and 1132/1990. However, the IRRS Team was informed that the Ministry of Health has limited ability to monitor the implementation of actions, required under the legal framework, in the Autonomous Communities.

There is currently a national project named MARR ("Risk Matrix in radiotherapy"). The project is promoted by the CSN and carried out within the FORO (Forum of Radiation Protection in Healthcare), together with the Spanish Radiotherapy Oncologist Society (SEOR) and Spanish Radiotherapy Technicians (AETR), and with the support of the Ministry of Health. The project aims at promoting the use and implementation of this risk methodology as a practicable measure to minimize the likelihood of unintended or accidental medical exposures. The Project MARR has been set up, for the period 2015-2020, as part of the National Patient Safety Strategy.

The Ministry of Development is responsible for policy and regulation related to transport on land, sea and by air. An agreement for collaboration with CSN was signed in 2015 for the regulation on the transport of radioactive materials.

The Ministry of Interior is responsible for emergency response in general. The CSN has General agreement in 2007 for collaborations. Coordination meetings among them are held periodically, and Ministry of Interior joins drill for nuclear emergency.

In 2013, agreements for Emergency Response support were signed between the Emergency Military Unit (UME) and each operating organization. CSN facilitated the arrangements contained in the agreements. Senior experts from CSN, UME, and the operating organizations meet periodically to discuss personnel training, drills, and equipment. In 2010, CSN and the UME signed an agreement to have a facility located at the Emergency Response Centre of UME as a back-up for the CSN's Madrid response facility. (See chapter 10).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The responsibilities for healthcare and regulatory control of medical exposure are distributed among: Ministry of Health, Ministry for the Ecological Transition, CSN and the Competent Autonomous Community. However, the IRRS team could not confirm if the Competent Autonomous Community are appropriately carrying out the effective control of medical exposure.*	
(1)	**BASIS: GSR Part 1, Requirement 7, Para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as: *(3) Applications of radiation in medicine, industry and research;* *This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience."*
(2)	**BASIS: GSR Part 1 Requirement 2 states that** *"The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated."*
R1	**Recommendation: The Government should establish mechanisms to ensure that the responsibilities assigned to the Competent Autonomous Community Health Authorities are effectively implemented.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The CSN and the Ministry of Health signed an MOU in 2010 to collaborate and cooperate on several topics. However, this MOU has not been systematically applied for the purpose of protection in medical practices.*	
(1)	**BASIS: GSR Part 1 Requirement 7, para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as:* *(3) Applications of radiation in medicine."*
S2	**Suggestion: The Ministry of Health and CSN should consider taking immediate steps toward applying the MOU for collaboration, signed in November 2010.**

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

Royal Decree 1836/1999 stipulates, in Article 81, that the public administration or the licensees, regardless of whether or not they are subject to this regulation, shall inform CSN of any event that might potentially lead to the radiological contamination of land or hydrological resources. The plans for the mitigation of effects or the decontamination of affected land or resources shall be submitted to CSN for review. Following the application of corrective actions, CSN shall inspect the area and re-evaluate its radiological conditions and may issue a report for appropriate action to be taken.

Royal Decree 783/2001 stipulates the role of competent authorities to intervene in case of lasting exposure, and the title-holders of occupational activities to carry out an assessment to determine whether there is a significant increase in exposure due to natural radiation sources. The competent authorities, e.g., authorities of Autonomous Communities, shall have report or advice from CSN before the intervention.

Royal Decree 229/2006 establishes the requirements applicable to orphan sources. ENRESA accepts recovered orphan sources.

Recovery campaigns for orphan sources were organized by MITECO, CSN and ENRESA in 2007 and 2008.

In 1999, CSN, Ministry of Industry, Ministry of Pubic Work, ENRESA, the Steel Company associations, and Spanish Recovery Federation signed a Protocol for cooperation on the radiological surveillance of metallic materials. That protocol (Spanish Protocol), although not required under regulations, expanded the participating members (currently 164 facilities, which is 98% of the relevant facilities in Spain) and 1824 detected radioactive materials were notified to the CSN in the past 20 years. The detected materials are systematically processed, stored and transported to the disposal with the cooperation of ENRESA. The IRRS team noted that Spanish Protocol for cooperation on the radiological surveillance of metallic materials have been working effectively over the past 20 years, contributing to prevent the loss of control of such materials and the associated radiological hazards.

A draft Royal Decree, specific to the identification and management of radiologically contaminated sites, has been prepared, but is pending approval. This draft Royal Decree addresses liability issues for radiologically contaminated sites, enforcement, restrictions on use and inventory issues. The IRRS team verified the existence of it as well as its content and is aware that an approval in due time is necessary in order to ensure protection and safety, for enhancing transparency, on the management of contaminated sites, and to support structured cooperation with other authorities. No specific guide exists for restoration of legacy sites. However, CSN guide 4.02 dealing with the on-site environmental restoration plan for facilities is considered as applicable. Upon restoration, the competent authorities will determine post-remediation measures or restrictions of use or access if necessary. At regional level, and for non-radiological contamination, public databases on contaminated land are maintained.

For the management of contaminated sites, Spain has regulations in place to deal with radiological (Royal Decree 783/2001 and Royal Decree 1836/1999) and non-radiological aspects (Law 22/2011, of July 28, on waste and contaminated land). This Law 22/2011 is applicable to Naturally Occurring Radioactive Material (NORM) contaminated sites and deals with requirements regarding liability, chemical contamination and waste minimization, restrictions on use and financing and property registration. Radiological legislation is not as complete as non-radiological legislation regarding management of contaminated areas. The IRRS team was informed that at present, no formal cooperation agreements exist with other authorities concerning the management of contaminated sites. During discussions with the counterpart, it was clearly pointed out that an integrated approach for the management of such sites is highly recommended. For the radiological component, CSN ensures that appropriate reference levels and protection strategies are established on a case by case basis.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although there is a Royal Decree under development addressing liability issues for radiologically contaminated sites, including the requirement for cooperation with competent authorities, currently CSN has no formal cooperation agreements in place relating to the management of contaminated sites.*	
(1)	**BASIS: GSR Part 1 Requirement 9, para. 2.26 states that** *"The regulatory body shall provide …. It shall establish the regulatory requirements and criteria for protective actions in cooperation with the other authorities involved, and in consultation with interested parties, as appropriate."*
(2)	**BASIS: GSR Part 1 Requirement 7, para. 2.18. states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
S3	**Suggestion: CSN should consider establishing cooperation agreements with other competent authorities regarding the management of contaminated sites**

1.7. PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL

Nuclear Energy Law stipulates that the Government establishes the policy and national programme on the management of radioactive waste, including spent nuclear fuel, and decommissioning of nuclear facilities, through the approval of the General Radioactive Waste Plan (GRWP). The plan shall consider the significant steps and milestones, concepts and technical solutions, the research, development and demonstration activities needed as well as the costing and financing aspects. The plan shall be regularly reviewed, and public participation shall be encouraged when drawing up the plan. Research on disposal is carried out by ENRESA and is considered in the ENRESA R&D plan. Every year ENRESA submits information on the national inventory of radioactive waste to CSN. The inventory was first completed in 2015 and includes all spent fuel and radioactive waste generated as well as estimates of future quantities.

The GRWP is developed by ENRESA and, according to Article 9.4, every four years or when otherwise required to do so by MITECO, ENRESA has to submit a revision of the plan to MITECO. The plan is further submitted to the Government, following a strategic environmental assessment, a mandatory review report by CSN and after having heard the Autonomous Communities in relation to land planning and the environment. The Government, after adopting the plan, shall subsequently notify the Parliament. Through the adoption of the GRWP, the Government establishes the national policy on the management of radioactive waste, including spent fuel, and the dismantling and decommissioning of nuclear facilities.

Royal Decree 1836/1999 provides the regulatory framework for dismantling, and requests that decommissioning is to be considered throughout the lifecycle of a facility, i.e., in site authorization, construction permit, operation permit. This Royal Decree requires to remove spent fuel from both reactor

and spent fuel pool as well as conditioning radioactive waste rising from the operation, prior to dismantling. Nuclear fuel cycle facilities and radioactive facilities are subject to similar requirements.

Royal Decree 102/2014 provides the regulatory framework for the responsible and safe management of spent fuel and radioactive waste. This Royal Decree attributes to ENRESA under the auspices of MITECO, the management of radioactive waste and spent fuel, as well as dismantling and decommissioning of nuclear and, where appropriate, radioactive facilities. The State is responsible for spent fuel and radioactive waste after the closure.

The "Fund for the financing of the General Radioactive Waste Plan" (Royal Decree 102/2014 Art 7.1) assures the financial provision for radioactive waste and Spent Nuclear Fuel (SNF) management and decommissioning of nuclear facilities. The fund is supported by taxation as prescribed in the 6th additional provision of Law 54/1997 of Electricity sector. ENRESA is charged with the management of the Fund, under supervision of an Interministerial Committee led by MITECO. The dismantling and decommissioning or closure of the radioactive facilities of the nuclear fuel cycle is not covered by this Fund. For these, the Royal Decree 1836/1999 charges the licensees, prior to entry into operation, to present a financial guarantee or bond, guaranteeing the future dismantling and management of the resulting radioactive waste. According to art. 41 of the Royal Decree 1836/1999, the licensees of radioactive facilities shall be responsible for their dismantling and decommissioning and hence also for a financial guarantee for it.

The IRRS team was informed that Spain applies the immediate dismantling of all nuclear facilities in the country, with the exception of the gas-cooled reactor of Vandellós I which has a 25-year waiting period ("dormancy phase") before dismantling.

The GRWP has not been revised since 2006. ENRESA has provided updates in 2010, 2013, 2014 and 2015 however these updated versions have not undergone formal approval by the government. Consequently, there is no formal basis for the current decision making in terms of the long-term management of radioactive waste, raising concerns regarding the sustainability of the current strategy for radioactive waste management.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The General Radioactive Waste Plan (GRWP) has not been revised since 2006. ENRESA has provided updates in 2010, 2014 and 2015 however these updated versions have not undergone formal approval by the government. Consequently, there is no formal basis for the current decision making in terms of the long-term management of radioactive waste, raising concerns regarding the sustainability of the current strategy for radioactive waste management*.	
(1)	**BASIS: GSR Part 1 Requirement 10 states that** *„The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel.* *2.28. Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities [3, 7]. The strategy shall include appropriate interim targets and end states. Radioactive waste generated in facilities and activities necessitates special consideration because of the various organizations concerned and the long timescales that may be involved. The government*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	shall enforce continuity of responsibility between successive authorized parties."
(2)	**BASIS: GSR Part 5 Requirement 2 states that** *„To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles and with international instruments, conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste."*
R2	**Recommendation: The Government should take immediate steps towards making decisions regarding updates to the GRWP such that the plan can inform decision making to ensure the continued safe and sustainable management, including interim storage and disposal, of radioactive waste in Spain.**

1.8. COMPETENCE FOR SAFETY

With regard to competence for safety, the Royal Decree 1836/1999 establishes the qualification needs of the staff of the regulated entities. In addition, the staff in relevant positions for safety in regulated entities needs to pass exams in front of examination boards set by the CSN to be able to get a diploma issued by CSN that certifies their qualifications in radiation protection and nuclear safety.

With regard to the competence for safety for the technical staff of CSN, Article 58 of CSN Statute states the following:

- The CSN shall promote the mechanisms and instruments necessary for the continuous training, improvement and technical specialization of civil servants in nuclear safety and radiation protection fields
- The specialization or improvement trainings taken by civil servants as well as aptitude certificates or diplomas obtained shall be recorded in their personal file in the Central registry of Staff of the General Administration of the State.

The CSN is currently developing a knowledge management process in response to the expected retirement of highly qualified staff.

The CSN obtains technical support from different organizations as necessary and takes into account the technical competence and independence of those organizations.

With regard to operators, based on Royal Decree 1836/1999 and the instructions on licenses for operational personal of nuclear power plants, training programmes on basic specific radiation protection matter, the CSN requires operators to have the competence for safety.

The CSN supports four University Chairs through research agreements and financial assistance, which contributes to the capacity building of future generations not only for CSN but also for entities involved in the application of nuclear and radiological technology.

1.9. PROVISION OF TECHNICAL SERVICES

Royal Decree 1836/1999 and Royal Decree 783/2001 stipulate the requirements for technical services, namely dosimetry, radiation protection services (internal service of the licensee) and radiation protection technical unit (external service), based on radiological risk. These Royal Decrees empower CSN to authorize, inspect or revoke authorization of the technical service.

With regard to environmental monitoring, CSN signed agreements with 21 laboratories and research centres belonging to universities in order to develop the monitoring programme for the atmosphere and the terrestrial environment, and with other official entities for monitoring the aquatic environment, where 10 laboratories accredited by National Accreditation Body (ENAC), the national accreditation entity designated by the Government, and the rest of them plans to be accredited. The CSN maintains an Automatic Station Network (REA) for the continuous measurement of atmospheric radioactivity.

1.10. SUMMARY

In general, the responsibilities and functions of the government comply with the IAEA safety standards.

The national policy and strategy for safety of Spain is mainly set out in Laws and the relevant Royal Decrees.

The CSN is able to take decisions under its statutory obligation for the regulatory control of facilities and activities and to perform its functions without undue pressure or constraint, based on CSN creation Law and the relevant Royal Decrees, while MITECO is the competent authority to issue licenses and to take enforcement measures, and has a role as a channel between CSN and the Autonomous Communities.

However, the General Radioactive Waste Plan (GRWP) has not been revised since 2006, and no formal basis exists for the decision making in terms of long-term management of radioactive waste. Therefore, the Government should ensure taking immediate steps toward the approval of updates to the GRWP.

Spain has opted for the strategy of immediate dismantling of nuclear facilities.

The following areas are identified as areas for further improvement:

- The Government: to make provisions to maintain the staffing level of CSN at the level necessary to achieve the safety objective and commensurate with the fees paid by the authorized parties
- The Ministry of Health and CSN: to take immediate steps toward applying the MOU for collaboration,
- The CSN: to establish cooperation agreements with other competent authorities regarding the management of contaminated sites

In addition, the following areas are identified as areas of good performance:

- CSN’s support to University Chairs in capacity building of future generations
- Effective implementation of Spanish Protocol for cooperation on the radiological surveillance of radioactive materials in scrap metals in the past 20 years

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Spain is a Contracting Party to all relevant international and regional conventions, expected for a country operating nuclear power plants. These conventions cover nuclear safety, emergency preparedness and response, nuclear liability, safety on spent nuclear fuel and radioactive waste management, and physical protection.

Spain complies with the provisions of the Convention of Nuclear Safety and the Joint Convention on the Safety of the Spent Fuel Management and on the Safety of Radioactive Waste Management, and:

- submits National Reports on the safety measures adopted by the country under the terms of the Conventions to the Review Meetings,
- attends Review Meetings,
- participates in country group meetings and in the exchange of questions and responses for clarification of the National Reports; and
- provides officers for the Country Group sessions.

Spain has registered its National Assistance Capabilities in the Agency's Response and Assistance Network (RANET).

Spain expressed its commitment to the IAEA Code of Conduct for the Safety and Security of Radioactive Sources with its Supplementary Guidance.

Spain has also subscribed to the commitments of the IAEA Guidance on the import and export of radioactive sources, complementary to the "Code of Conduct on the Safety and Security of Radioactive Sources".

The CSN participates in the IAEA Safety Standards Committees on nuclear, waste, radiation and transport safety (NUSSC, WASSC, RASSC, TRANSSC) and on emergency preparedness and response (EPReSC). CSN also participates in the Commission on Safety Standards (CSS). The IAEA Safety Standards have served as fundamental references and benchmarks to CSN for nuclear safety and radiation protection, and for developing safety instructions.

The CSN is a member of several international regulatory forums, being founder members of them:

- Western European Nuclear Regulators Association (WENRA);
- Head of European Radiological Competent Authorities (HERCA);
- Foro Iberoamericano de Organismos Reguladores Radiológicos y Nucleares (FORO) and
- International Nuclear Regulators Association (INRA).

In addition, CSN maintains twenty-one separate bilateral agreements with other IAEA Member State nuclear safety regulatory authorities, among which, in particular, it sustains regular exchange of activities on regulatory matters with eight Member States. These arrangements provide the CSN with a mechanism for information sharing and technical cooperation on various aspects of nuclear safety and radiation protection. Spanish experts also participate in international peer review missions such as IRRS, ARTEMIS and EPREV.

Spain participates actively in the assistance programmes of the IAEA´s Technical Cooperation and the European Commission Instrument for Nuclear Safety Cooperation (INSC) projects.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The CSN has established a dedicated procedure for receiving information from other States and authorized parties and for carrying out analysis to identify lessons learned from operating experience. This function is done within the Technical Directorate of Nuclear Safety (for NPPs operation) and Directorate of Radiation Protection. As noted above, CSN has multiple bilateral and multinational agreements in place where operational and regulatory feedback is shared, through IAEA, HERCA, WENRA, FORO, US-NRC and INRA. Where appropriate, experience feedback is considered in the CSN by the Technical Directions and incorporated into technical instructions and practices based on the specific analysis on their added value.

The CSN requires nuclear facilities authorization holders to implement procedures for operating experience collection and extracting lessons learned from internal and external sources through conditions of authorizations.

In response to the Fukushima Daiichi accident, the Government participated in the IAEA Ministerial Conference on Nuclear Safety and the Second Extraordinary Meeting on the Convention on Nuclear Safety. A National Nuclear Safety Action Plan was put in place to address the lessons learned from the Fukushima Daiichi accident and the CSN engaged in a re-evaluation process based on the results of the European Stress Tests and made specific requests to license holders through complementary technical instructions. There are further examples on how CSN has extracted lessons learnt from international and local operating experience feedback through discussion panels to review them and shared according to their relevance.

2.3. SUMMARY

CSN has a high level of international cooperation and fulfils the international obligations by participating in the relevant international arrangements, including international peer reviews, and by promoting international cooperation to enhance safety globally.

All the necessary elements of operational and regulatory experience feedback are in place, and activities related to operating experience feedback at the CSN are deployed in a structured and systematic way in line with international practices.

The work done by CSN for the global safety regime does not only help Spain to increase its capabilities for nuclear and radiation safety, but also, it is a relevant contribution towards increasing safety worldwide, in all the reviewed areas. Therefore, this capability was agreed to be considered as good performance of the CSN.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

The main organisational units of CSN are the Board, General Secretary, Technical Directorate for Nuclear Safety, Technical Directorate for Radiation Protection, Inspection unit, Research and Knowledge Management unit, Planning, Evaluation and Quality unit and units for Legal Services, Administration and Information Technology. This organisation structure is defined in the Statute of CSN, the Royal Decree 1440/2010.

The organizational structure reflects the duties of CSN, and the different activities and facilities to be supervised. The resources are allocated based on the tasks of the different units, but resources can also be used across the organisational interfaces. A graded approach is embedded in the requirements directed to the licensees as well as in the internal procedures for assessment and inspections. Radioactive facilities are categorised according to their associated risk, whereas no such categorisation is done for nuclear facilities. The implementation of graded approach is thus reflected in the supervision activities required from the CSN, and in the allocation of resources.

The Board consists of a President and four Council Members, appointed by the Government. The President and the Council Members are selected for a six-year-term, the number of terms is limited to two. The appointments of the Board Members must be accepted by the Parliament.

Also, the heads of the Technical Directorate for Nuclear Safety and of the Technical Directorate for Radiation Protection are appointed by the Government at the suggestion of MITECO.

All significant regulatory decisions of CSN are made by the CSN Board in plenary. On the other hand, the Plenary Assembly does not have the power to change the structure of the organisation described in the Statute (1440/2010). Any changes to the Statute are subject to approval from the Government.

The IRRS team considered the organisational structure to be appropriate and able to support efficient discharge of CSN's statutory functions, as defined in Law 15/1980. However, the IRRS team observed that, while changes to the organisational structure can be proposed by CSN, it is in reality never done. The major reason is the slow and cumbersome process for implementation of a proposal for an organisational change through Government approval for a change of the Statute. CSN mitigates potential negative impacts of the constrained structural flexibility by establishing teams and projects that bring together expertise from different organisational units for particular purposes. Indeed, CSN management refer to the structure and operations of CSN as a 'matrix' model. It is noted by CSN management as well as by the IRRS team that while the model may seem inflexible, it also provides stability. For example, the stable division between the two technical 'Directions' (Nuclear Safety and Radiological Protection, respectively) may support long-term development to enhance organisational performance in these two important areas.

Nevertheless, the IRRS team is of the view that CSN should be given increased authority to optimise its organisational structure to deliver on its statutory functions in the most efficient and effective way.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *As the organisational structure of CSN is established by statute, CSN has limited flexibility to adjust its organisation, as government approval through statutory amendment would be required.*	
(1)	**BASIS: GSR Part 1 Requirement 16, para. 4.5. states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively."*
S4	**Suggestion: CSN should consider engaging in a discussion with government, to obtain the flexibility to adjust its organisational structure.**

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The foundation for independence of CSN is given in the legislation. Legislation describes CSN's governmental position, regulatory duties as well as regulatory powers. CSN is a governmental organization for the regulatory control of the use of radiation and nuclear energy. The legislation defines no other responsibilities or duties which would be in conflict with regulatory control.

According to Royal Decree 1440/2010, every inspector of CSN has the authority to stop any activity that is an immediate risk to nuclear or radiation safety.

CSN has resident inspectors on the sites of nuclear facilities, except for Juzbado fuel manufacturing plant and disposal facility for LILW of El Cabril. The resident inspectors have broad authorities; they can attend all the meetings on site and observe any activities.

The technical competence and the possibility to use external expert organisations support the independence of CSN from the licensees in technical matters. It is clear that the advice and assistance from external organizations does not relieve CSN of its assigned responsibilities. The final responsibility with regard to decision making rests with CSN.

For avoiding conflict of interest, CSN applies for example the means described below.

CSN has a Code of Ethics that discusses independence, integrity and neutrality, among other things. In the preparation of the Code of Ethics, the staff had opportunity to provide input and present questions and concerns that should be considered in the document. Role of CSN and its independence are also addressed in the initial training.

The stay of the resident inspector on one site is limited to 10 years to maintain objectivity in performance of their duties. In addition, the resident inspectors are in close contact with CSN headquarters, for example they hold daily telephone conference.

If staff member is hired from an authorized party, there is a 2-year-period during which the person cannot be involved in the regulatory control of his/her previous employer.

The independence of external support organisations is required by the law (15/1980) and is addressed when procuring services.

The involvement of CSN staff in other professional activities is bound by the state laws governing civil servants. Royal Legislative Decree 5/2015 (Civil servant basic law) discusses management of conflict of interests.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

Most of CSN staff are Civil servants. They have academic degrees and have passed a rigorous selection process including written and oral examinations. CSN has a comprehensive training programme for its staff. The training needs are gathered annually from the different organizational units. The Research and Knowledge management unit (IDGC) has the responsibility to develop training programmes and to evaluate their results. IDGC is supported by other units in defining the content of the training programs. The annual training plan is approved by the CSN Board in plenary. The IRRS team was informed that on average 6-7 % of working time is used for participation in training.

Despite the comprehensive training programme, the IRRS team observed that a more systematic approach to training might be beneficial to CSN, in order to maintain the present high level of competence and establish qualification standards. In addition, there is no specific qualification or certification required before a staff member is allowed to perform inspections. Furthermore, the mandatory training requirements, especially for refresher training, are not defined in detail for staff having a position in CSN's emergency response organisation. The IRRS team also observed that the effectiveness of training is not evaluated systematically. Training related observations are discussed further in Modules 7 and 10.

Annual resource planning is based on the annual work plan; it takes into account the known retirements. The main input for the annual working plan is the information gathered from the authorized parties. Also needs to develop new regulations or CSN's processes are considered. Based on the annual working plan, the number of needed staff is determined and results in an annual resource plan. The recruitment plans are subject to Government's approval.

For long-term planning, a human resource policy was drafted for years 2014-2019. It described the prevailing situation and discussed the objectives of resource management as well as funding of CSN. The policy is due to be updated next year. The update is planned to include job descriptions and a plan to maintain CSN's competences both in short and long term. The present version of the human resource policy does not discuss in any detail the actual number of staff needed for performing the duties of CSN.

The competence needed in long-term is considered using as input the known retirements, the plans of the licensees (e.g. to start using new technology), the information gained due to participation in research projects or in different international activities. If the need for the new competence is permanent, training of CSN's staff or recruitment of experts is considered. If the need is only temporary, external support organisations can be used to cover the gap in competence. At the time of the mission, the long-term competence needs were not recorded systematically, even if the importance of long-term planning was recognised and considered in different contexts. Module 6 discusses the same issue from the point of view of review and assessment. The IRRS team considers that CSN would benefit from a more systematic resource planning (covering both numbers of staff and needed competence), addressing especially long-term needs. See also chapter 9.4 and ARTEMIS Recommendation 3b on CSN's role in the implementation of the GRWP and the establishment of a deep geological disposal facility. CSN has recognized that development of a human resource plan is an opportunity for improvement. This was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission

A challenge for maintaining competence in case of retirements is that no overlap in the working periods of the retiring expert and his/her replacement is allowed in the civil servant system. CSN started development of knowledge management in 2013 due to the fact that during the period 2014-2018 a number of retirements was expected. CSN first identified the positions that were the most critical (relation to core functions, only a limited number of experts). The knowledge of the chosen 16 retiring experts has been recorded in various ways, using written documents, interviews and video recordings. The information is gathered into a tool

that is available in the Intranet. In the future, each expert will have his/her own "knowledge book" in the tool, not only those approaching retirement.

The expenses of the regulatory oversight are collected from the regulated parties. The fees to be paid are defined in Law 14/1999. For environmental monitoring, CSN receives funds from the state budget every year. However, even if the expenses of regulatory oversight are covered by the fees, CSN has experienced episodes of restricted ability to recruit new staff due to restrictions by the Government on the number of Civil servants. This is captured by Recommendation 1 in Module 1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *CSN provides significant training for its staff but lacks a systematic approach. This observation applies to defining the training and qualifications required for specific tasks and positions (e.g. inspectors or emergency responders).*	
(1)	**BASIS: GSG-12, para. 6.45 states that** *"Inspectors should be experienced and capable of working without direct supervision and should have the necessary skills so as to be able to represent the regulatory body adequately without being drawn into the authorized party's decision making process."*
(2)	**BASIS: GSG-13, para. 3.262 states that** *"The regulatory body should issue internal guidance for its inspectors on performing regulatory inspections…. Each inspector should be given adequate training in following this guidance."*
(3)	**BASIS: BASIS: GSR Part 7 para. 6.28 states that** *"The operating organization and response organizations shall identify the knowledge, skills and abilities necessary to perform the functions specified in Section 5. The operating organization and response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel selected have the requisite knowledge, skills and abilities to perform their assigned response functions. The arrangements shall include arrangements for continuing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities in an emergency response undergo the specified training."*
S5	**Suggestion: CSN should consider enhancing its training activities by establishing a more systematic approach to training and by considering formal qualification for certain positions.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although CSN's approach to human resource planning is captured in several different documents, a comprehensive and consolidated Human Resource Plan would identify the long-term resource needs, including the required competencies for emerging technologies.*	
(1)	**BASIS: GSR Part 1 Requirement 18, para. 4.11 (X) states that** *"A human resource plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities."*
(2)	**BASIS: GSR Part 1 Requirement 18, para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
(3)	**BASIS: GSG-13 Para 6.24 states that** *"The introduction of new types of facilities or new activities, the introduction of novel technologies, the ageing of facilities or the passage of a facility to another stage of its lifetime should be considered in the planning of competences and in the adaptation of training programmes".*
S6	**Suggestion: CSN should consider creating a consolidated and comprehensive Human Resource Plan.**

Policy issue No 2: Human Resources

The discussion targeted the policy for human resources, the models and mechanisms used by different countries for ensuring among other things the following: the proper management and maintenance of human resources commensurate with the nature and the number of facilities and activities to be regulated; consideration to staff rotation; attraction of talented graduates; and how to incentivise highly skilled staff to assume more demanding responsibilities.

CSN has already developed and implemented most of the key elements required for an adequate capacity building. However, CSN recognized their need to review and update their policy on Human Resources to include the job descriptions and carry out a plan to maintain CSN competences available at a short and long-term.

The recruitment plan and strategies vary from country to country. Nevertheless, the majority of the countries in attendance expressed that they have both authority and flexibility to recruit as needed and as feasible within the budget. Furthermore, it was emphasized that a specific training programme based on an analysis of the necessary competence and skills over coming years is needed, which should also be developed by management and identification of specific training requirements. As an example, some countries mentioned their promotion strategy to attract talented graduates, by providing internships and agreements with the State's Universities in areas related with nuclear applications. Others mentioned the need to prevent the establishment of organisational 'silos' in order to enable the utilisation of expertise across different areas to achieve defined organisational objectives. These agreements also enhance the ability to provide adequate safety competence at the national level with identification of the national stakeholders for establishing and implementing a national strategy for training, including defining their role, responsibilities and expected contributions.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

CSN has prepared a draft policy concerning establishing Technical advisory committees. The IRRS team was informed that the policy discusses the situations, where the advisory committee could be used to support CSN's work. The draft is in the approval process.

Royal Decree 1440/2010 enables the use of external support and articulates the requirement for the independence of the support organization. Royal Decree 1440/2010 states also that persons that do not belong to CSN staff shall in no case take direct part in the decision-making. Therefore, the entire responsibility of decision-making rests with CSN despite the use of external support.

When the technical directorates would like to use external support, they draft a justification for the use of external support, and description of the work to be performed. The legal department and administrative department then perform the procurement according to the internal rules of CSN (PG.V.03). The qualification requirements to perform the work are specified in the call for bids. The selection of the contracted organization is made by a panel consisting of the general secretary, financial controller of the government and representatives from the technical unit needing the service and from legal and administrative departments. The requisite of independence is developed in the contracting clauses. The CSN Board finally approves the use of external support. CSN has some long-term contracts with universities for environmental monitoring and for laboratories in dosimetry services. For those, CSN makes benchmark tests from time to time to evaluate the quality of their work.

Regarding radiation protection, Spanish legislation recognizes three types of technical services: Dosimetry services, Radiation Protection Services (RPS) and Technical Unit of Radiological Protection (UTRP).

CSN issues authorization of services and units. Radiation Protection Services (RPS) is a part of a licensee. A Head of an RPS should also be licensed by CSN. At the time of the mission there were about 90 authorized RPS. In addition, when Radiation Protection Supervisor is required the supervisor should also be licensed by the CSN.

In case that an applicant for registration or already registrant needs an advice or verification of radiation protection measures such advice and verification can be given by an external organization, i.e. Technical Unit of Radiological Protection (UTPR). At the time of the mission there were about 40 UTPR in Spain. Authorization and inspection of UTRP is assured by CSN.

Conditions regarding mentioned authorizations are given in Royal Decree 783/2001, which approves the Regulation on Sanitary Protection against Ionising Radiations.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

CSN has established both formal and informal communication channels with the authorised parties.

The regulatory decisions and inspection reports are sent by official channels. The decisions include the justification for the decision (the applied laws and CSN's evaluation of compliance with the requirements). It is a common practice to be in contact with the applicant during the review of an application, to discuss matters and clarify any unclear points. Formal and frequently used mechanisms of liaison are the inspections of the authorized activities and facilities.

CSN assigns a project manager for the oversight of each nuclear facility. The project manager is regularly in contact with the licensee. Meetings are arranged when needed, but also on regular basis. For example, four times a year a meeting is arranged with the management (deputy director) of each facility. From CSN, the project manager and respective deputy director attend the meeting. There are informal meetings between the top management of the facilities and CSN Board.

For radioactive facilities different from fuel cycle facilities, CSN meets the authorized parties mainly through common working groups and other fora, where the related professional societies, for example Society of Radiation Protection and Society of Health-Physics, are represented.

The resident inspectors at the nuclear facilities are an important link between CSN and the licensees. The resident inspectors are in direct and continuous contact with the licensee's staff when observing the day-to-day work at the facilities, performing inspections and attending meetings of the licensees. The rules and principles for liaison between the licensees and the resident inspectors are documented in CSN instruction IS-14.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The basis for the regulatory control are the requirements established in the Nuclear Energy Law, Royal Decrees and in the CSN's instructions.

Regulatory activities and core processes are detailed in the management system. CSN has established procedures to guide the staff in performing review and assessment, and inspections.

All significant decisions are made by the CSN Board in plenary. This minimizes subjectivity in decision-making, as no decisions are made by an individual staff member. Moreover, the evaluation reports prepared by staff involved during the safety assessment of an application are reviewed by the respective unit's heads. If CSN does not approve an application, it is obliged to give the justification for the negative decision to the applicant.

All decisions are recorded in a database. Thus, the previous decisions made on similar matters are available. It is possible to make different type of searches in the database; it is possible to search by an individual word, or by facility. In the database, some ready-made searches by topic (e.g. radiation protection, security) are available. This helps to ensure consistency among regulatory decisions.

Changing regulatory requirements presented in the Royal Decrees and CSN's instructions is possible following a defined process. The process includes participation of the involved parties and general public, as well as the CSN Board's decisions made in the plenary meetings. The complementary instructions that are specific to a certain facility or licensee do not go through the same process. The process of developing regulations and guides and the difference in the process for Instructions and Complementary instructions are discussed in more detail in Module 9.

3.7. SAFETY RELATED RECORDS

CSN maintains records of radioactive sources and radiation generators (IRA). In the IRA database, all documentation related to the source is recorded. The documentation includes documents supplied by the applicant and decisions by CSN. Performed inspections are included in the register, too.

Occupational doses are recorded in the National Dosimetry Bank (NDB).

Results of environmental monitoring are recorded in database KEEPER. This database is a powerful tool for the assessment of the data by the experts of the Environmental Radiation Protection Deputy Direction and also accessible to the public. Recommendation 2004/2/EURATOM on the control of radioactive discharges, not mandatory until the transposition of Directive 2013/59/EURATOM, has been required and applied in Spanish nuclear power plants since 2007. Discharge data, including isotopic composition, are sent to CSN for each discharged batch. It allows CSN to rapidly evaluate radiological impact by combining environmental monitoring data available on KEEPER with detailed discharge data in case of detected anomalies, or for the preparation of inspections.

Detailed information on every discharge of radioactive effluents is submitted monthly by licensees and stored in the CSN effluent database (ELGA).

Events on nuclear facilities are recorded in database called FIO. The record goes back to early 70's. CSN instruction IS-10 defines the criteria for events to be recorded, and the information the licensee must provide to CSN.

For events on radiological installations, a database (SUCRA) was established in 2016. The CSN instruction IS-18 defines the criteria for events to be recorded and the information the licensee must provide to CSN. The database covers also events during transportation.

Information relating to the safety of facilities and activities and that might be necessary for shutdown and decommissioning, is recorded in CSN's document management system. The system includes, for example, the licensing documentation of the facilities, information concerning modification, issued authorizations and inspection reports.

CSN also records the inventories of radioactive wastes and of spent fuel. The inventories are reported annually to the Parliament.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

A Communication plan has been developed that describes the strategy and objectives of communications with interested parties, which are identified in the Management System Manual. The goals are set separately for external and internal communication, and for communication during radiological emergencies.

The Cabinet of the President has a unit (COMU) responsible to coordinating communication. Most of the staff in the unit are communication experts, e.g. former journalists. CSN's procedures related to communication consider also the use of social media.

The Cabinet of the President has a unit (RRII) responsible for coordinating the liaison with other governmental authorities.

CSN uses it website extensively for informing the general public about its duties, nuclear and radiation safety, current issues and results of regulatory oversight. Many documents of CSN, like for example the Code of Ethics, Training Plans, Strategy Plan and Annual work plans are also publicly available. The regulatory decisions together with the related application documents are published on the website. Also, inspection reports are published. The internal evaluation reports of CSN are available to the public on request, providing they do not include personal information, proprietary or security-related information. An email address is provided on the website for questions and comments from the public.

CSN communicates with the Parliament, which also represents the public. CSN prepares a comprehensive annual report to the Parliament and may also attend meeting of Parliament to discuss important topics. The meetings and topics can be proposed by the Parliament, but CSN can take the initiative itself, too. CSN participates in the meetings of the local parliaments of the autonomous communities when necessary.

For informing the public and other interested parties about the public and environmental exposure, CSN has a comprehensive information package on its website, including access to the KEEPER database. The information available includes:

- real-time monitoring of radioactivity in the atmosphere through the Automatic Stations Network (REA), showing the daily and monthly mean values of gamma dose rate on a map;
- detailed information on the results of the environmental monitoring through the KEEPER database tool;
- annual reports on the environmental monitoring results;

- collection of 18 procedures regarding harmonization of practices for environmental monitoring, sampling and analyses (soil, water, milk…);
- Radon risk map indicating prone areas exceeding 300 Bq/m³ at ground level;
- legal and regulatory documents related to the main missions of CSN.

The IRRS team verified the existence and content of the information available on the website and had a demonstration of the KEEPER database. The IRRS team considers that providing access to the public to data regarding public and environmental exposure and environmental monitoring is good performance.

Spain has signed a Memorandum of Understanding (MoU) with the European Union to publish the measured values of the Automatic Stations Network (REA) in the European Radiological Data Exchange Platform (EURDEP). EURDEP is connected with the IAEA tool called the International Radiation Monitoring Information System (IRMIS).

The drafts of regulations (Royal Decrees) and CSN instructions are open to comments from public. Each comment is answered by CSN, and the conclusion on the resolution of each comment is recorded in the minutes of the plenary meeting where the concerned draft is discussed. The minutes are published on CSN's website. The CSN instructions are also sent to the Parliament and the European Commission for comments.

For enabling public involvement in important decision, CSN is not the only organisation with duties towards the public. In the framework of the Environmental Impact Assessment processes, MITECO has the responsibility to arrange a 30-day period for public involvement for establishment of a new facility. On case-by-case decision, MITECO can arrange corresponding period also in case of important decisions during the facility's lifetime, e.g., for significant modifications.

Regarding the duty of the authorized party to inform the public about the possible risks associated with the facility or activity, the approach is to oblige (Royal Decree 1836/1999) the licensees of nuclear power plants to participate in the Local Information Committee. The committee includes representatives of the municipalities in the vicinity of the facility and regional delegates of the government. Duty of the local information committee is, among other things, to inform the different entities represented of the development of the regulated activities. This approach does not fully meet the IAEA Safety Requirements related to communication and information of interested parties by the authorized parties. The authorized party cannot control how the representatives of the municipalities share the information from the committee to the general public. Furthermore, it is not clearly required that the risks associated with the facility should be included in the information provided. The obligation set up by Royal Decree 1836/1999 is only addressed to nuclear power plants, excluding other nuclear and radioactive facilities.

In case of events or any matters that cause public concern, CSN can meet the public in the vicinity of the facility in question. Purpose of these meetings is to inform the public and answer their questions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The regulatory body does not require all relevant authorized parties to inform the public about radiation risks and other relevant information associated with their facilities or the conduct of their activity.*	
(1)	**BASIS: GSR Part 1 Requirement 36, para. 4.68 states that** *"The authorized party shall inform the public about the possible radiation risks (arising from operational states and accidents, including events with a very low probability of occurrence) associated with the operation of a facility or the conduct of an activity. This obligation shall be specified in the regulations promulgated by the regulatory body, in the authorization or by other legal means."*
R3	**Recommendation: The regulatory authorities should require the relevant authorised parties to inform the public about the possible radiation risks associated with their facilities and activities, in accordance with a graded approach.**

3.9. SUMMARY

Overall, the responsibilities and functions of the regulatory body comply with the IAEA safety standards. However, the following areas, where further improvement is possible, were identified:

- the possibility for CSN to optimise its organisational structure
- human resource planning, especially for long-term needs
- training, in order to maintain the present high level of competence
- regulatory provisions for the authorized parties to inform the public about risks associated with their facilities.

It was identified as good performance, that CSN provides the public comprehensive information about environmental exposure, including access to the results of environmental monitoring through KEEPER database.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

CSN has formulated, in several documents, its mission, vision and values, which aim at providing a framework for individual and organizational expectations. This is a visible demonstration of the senior managers' leadership and commitment to safety. Moreover, Principle 1 of the CSN Safety Culture Policy requires that senior management and managers at all levels lead organization in a way that safety is always an overriding priority and that leadership for safety is demonstrated at all levels in the organization. CSN has also a set of several policy statements, not covered in one single policy document, namely:

- Policy on safety;
- Policy on efficiency and effectiveness;
- Policy on transparency;
- Policy on independence;
- Policy on external relations;
- Policy on inspections;
- Policy on human resources and providing resources;
- Safety culture policy;
- Information system security policy.

Policies, mission, vision, values and strategic plan are communicated to CSN employees according to the CSN communication plan, via the Intranet, including other key managerial documents such as the CSN annual workplan and CSN policies i.e., the Policy on inspection and Policy on Safety Culture. The Policy on Safety Culture was introduced by the technical director of nuclear safety to the entire CSN Staff.

However, the wording of the organizational values in the Strategic Plan, Management System Manual and Code of Ethics is not always the same.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

Goals, strategies, plans and objectives of CSN are established by the CSN Board. They are reflected in CSN Strategic Plan and an associated annual workplan. This later encompasses activities of all departments. It consists of two parts. The first one, published on CSN Website, lists the most significant activities and defines number of inspections for specific facility. The second part consists of nine annexes which cover all other activities to be implemented in the current year.

Strategic safety goals are established by CSN Strategic Plan and reported annually to the Parliament. They are further detailed by measurable safety objectives described in the annual workplan. Strategic goals are annually reviewed meanwhile the implementation progress of the annual workplan are reviewed and reported quarterly accordingly. Where necessary, actions are taken to aim at meeting the expected results.

On a weekly basis, the department management committee of each technical directorate reviews the objectives related directly to nuclear or radioactive facilities. These reviews are based on the use of internal IT tools: PROA to monitor the performance of inspection activities, evaluation activities and other activities related to the annual workplan and INUC used only for nuclear installations. Within these tools all duties, responsible persons for implementing duties and deadlines are recorded. For the other parts of CSN, the department or unit heads are responsible for the implementation of their part of the annual workplan. Other IT systems are used for monitoring the implementation of the other activities.

Every three months Planning, Evaluation and Quality Unit (UPEC) collects from all CSN departments, the inputs on implementation progress of the annual workplan. Then, UPEC prepared a report on status of the annual workplan implementation and it is presented to the CSN Board.

4.3. THE MANAGEMENT SYSTEM

The CSN has established and implemented a process-based management system which integrates all functions and activities implemented in CSN. The system was developed in accordance with the previous IAEA safety standard GS-R-3 *The Management System for Facilities and Activities.* However, CSN has initiated the revision of its management system in order to meet the requirements of the new IAEA Safety Standard GSR Part 2 *Leadership and Management for Safety*.

The organizational structure of CSN, responsibilities and accountabilities at different levels of CSN are specified in the Management System Manual and in the Organisation and Operation Manual, as appropriate. The Management System Manual also describes organizational processes and their interfaces and the relation with external organizations.

It is clearly stated in the Management System Manual that the CSN Board is responsible for establishing, applying, sustaining and continuously improving the management system to ensure safety. To discharge effectively these responsibilities, CSN has set up a "Management System and Information Security Committee". This committee consists of the following CSN senior managers:

- Two commissioners;
- General secretary;
- Technical director for nuclear safety;
- Technical director for radiation protection;
- Deputy director for administration and human resources;
- Deputy director for information and communication technology;
- Director of the cabinet of the CSN president;
- Head of the planning evaluation and quality unit, who is responsible for coordination of the management system.

The Committee is responsible, inter alia, to:

- Propose CSN's management system strategy, to develop it and oversee its implementation;
- Review the draft management system documentation prior to their approval;
- Analyse the assessments of the processes and activities;
- Propose and monitor the improvement actions.

The necessary arrangements for an independent review to be made before decisions significant for safety will be implemented within CSN Technical Advisory Committees, addressed in subchapter 3.4 and are not implemented, yet. The criteria for identification which type of decisions should go through an independent review will be set up.

The need for flexibility and CSN authority to optimise its organisational structure is addressed in Section 3.1. Organizational changes should be also covered by the management system. However, CSN does not have any provisions in the management system for identifying and analysing organizational changes which may be needed for CSN to deliver its statutory functions in the most efficient and effective way. This was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The CSN management system does not include provisions to identify and assess organizational changes necessary to optimise its organisational structure and composition for efficiency and effectiveness.*	
(1)	**BASIS GSR Part 2, Requirement 6 para 4.13 states that** *"Provision shall be made in the management system to identify any changes (including organizational changes and the cumulative effects of minor changes) that could have significant implications for safety and to ensure that they are appropriately analysed."*
(2)	**BASIS: GSG 12 Appendix II para II 24 states that** *"The regulatory body should put in place a process for managing organizational change for changes made in response to external or internal initiatives. The process should ensure that the potential impact of proposed changes on the effectiveness of the regulatory body is systematically assessed. Changes should not be implemented without adequate review and should be modified (e.g. by means of compensatory measures) if they impact negatively on the effectiveness with which the regulatory body discharges its mandate. "*
S7	**Suggestion: CSN should consider establishing a process to identify, assess and implement organisational changes.**

CSN developed two administrative procedures dealing with conflicts which may arise during decision making process: Procedure PG.IV.8 for conflicts arising before the final decision is made, and procedure PA.XI.33 for conflicts arising after the final decision is made.

The graded approach applied by CSN is defined in the Management System Manual in section 2.3. The graded approach is mainly applied in the operating (core) processes of CSN, such as evaluation process or inspection process.

The management system documentation comprises among others:

- The Management System Manual. The version at the time of the mission was issued in 2012. It includes: CSN mission and vision, policies, role and responsibilities of CSN, description of the overall organization, description of processes, and references to procedures. The management system manual is planned to be revised to comply with GRS Part 2;
- The Organization and Operation Manual, which describes the structure of the organization and the allocation of responsibilities necessary to fulfil the functions of CSN;
- The Processes Map;
- The Procedures.

There are three types of Management System Procedures: Management Procedures (MP), which describe the processes defined in the process map, Administrative Procedures (AP), and Technical Procedures (TP). All management system documents are available on the Intranet.

Records for the implementation of the management system are identified in the management system documentation. Some retention times for keeping certain types of records are identified in legislation i.e., the need for - and the duration of - the maintenance of individual dose records is addressed in RD 783/2001, of 6th July, which approves the Regulation on Sanitary Protection against Ionising Radiations, art.34 and

38. However, CSN does not have comprehensive provisions to manage records under its management system. That should include a record retention schedule providing retention time of different types of records and other necessary information to ensure the proper conservation of records in accordance with the statutory requirements and with the obligations of CSN for knowledge management of its organization. All additional records necessary for the effective implementation of the management system should be also taken into account. This issue was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *CSN has identified the records required for inclusion in its management system. However, the CSN has not established associated retention times consistent with the statutory requirements and ensuring the proper implementation of the management system.*	
(1)	**BASIS: GSR Part 2, Requirement 8 para 4.20 states that** *"Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and with the obligations for knowledge management of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record."*
(2)	**BASIS: GSG-12 Appendix II para II.14 states that** *"The process for control of records should ensure that records:* – *Are categorized;* – *Are registered upon receipt;* – *Are readily retrievable;* – *Are indexed and placed in their proper locations in the files of the record facility with the retention times clearly specified;* – *Are stored in a controlled and safe environment;* – *Are stored in appropriate storage media;* – *Remain unchanged under normal circumstances.*
R4	**Recommendation: CSN should establish a record retention schedule to define the required retention times for each type of records, the associated responsibilities, the record format and support, and the record storage location.**

4.4. MANAGEMENT OF RESOURCES

The CSN Board approved the Policy on Human Resources for the period 2014 – 2019 in 2014. This policy includes job descriptions only for new positions approved by the Policy. The Organisation and Operation Manual defines the needed competences but only at departmental and unit levels. The Policy for the upcoming period will consider the foreseen retirements, need for recruitments, and the needed trainings for newcomers in order for them to get the relevant level of competences for their assigned work in CSN. This Policy is also expected to include job descriptions and plan to maintain CSN competences on short and long-term periods.

A knowledge management system is under implementation to take into consideration the knowledge needed, resources available and expected retirements to maintain the right level of competence of CSN. The CSN is also developing a software to manage human resources, including to assign adequate tasks at the appropriate staff.

The managers are responsible to elaborate the training programme based on their actual qualification and competence needs for their unit. The CSN Board approves annually the overall training programme of the organization.

To support the audit programme of CSN, 25 CSN employees were trained internally 9 years ago. To increase the auditors pool, two CSN employees (from UPEC) were recently trained for ISO 9001 internal auditors at the Spanish Association for Quality in order to gain the knowledge on auditing technics.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

CSN integrated management system has been developed using a process-based approach. Processes are documented in the Process Descriptions in Annex VII of the Manual and its associated procedures. The sequencing of the processes and their interactions are specified in the management system.

The processes are identified as strategic, operative or support processes. Overall, these process types are in line with the typical grouping of processes proposed by GSG-12, i.e., managerial processes, core processes and support processes. Nevertheless, inconsistencies with GSG-12 have been identified and few processes are not allocated to right type as proposed by GSG-12. Typically, the core processes derived from the core functions of the regulatory body is categorized by CSN as operative processes, however the process for the preparation of regulation is categorized as a strategic process. Another example is the process covering the management system review categorized as a support process in the CSN management system structure whereas it concerns with the management of the regulatory body. Even if the process categorization appears to be less than optimal in light of GSG-12, no evidence of significant problem has been identified.

For each process, the process owner, the person responsible for managing the processes, is identified. At the time of the mission, the process owners were the general secretary, heads of directorates and director of the cabinet of CSN president. CSN identified that the responsibility of process owner is, for some process, assigned at very high hierarchy level. The revision of the management system will be an opportunity to appoint suitable process owners.

Given the legal requirements, it turns out that the outsourcing activities for CSN is time consuming and requires many administrative and planning procedures to be implemented. Consequently, CSN outsources activities are provided only for large projects such as the Centralized Storage Facility or for specific low-cost amount activities such as trainings.

Provisions for outsourcing activities are covered by the management system. CSN developed procedure PG.V.03 Management of external suppliers approved in 1997. But, the review of the documentation showed that the procedure for the management of external suppliers and services, approved in 1997, has not been harmonized with the Law 9/2017 on Contracts Applied to Public Sector. However, this procedure is still under revision.

4.6. CULTURE FOR SAFETY

CSN recognizes the importance of safety culture and has taken action to foster and support a culture for safety within CSN. An ad hoc working group was established to develop the CSN Policy on Safety Culture. The comprehensive document Policy on Safety Culture establishes five principles and associated attributes that support the CSN's safety culture. The CSN staff was involved in the development of the policy and had opportunity to comment the draft. All comments were addressed by UPEC. Policy on Safety Culture

was eventually approved in January 2017 by the CSN Board and published on Internet. A specific presentation was made to the CSN staff in June 2017. In addition, the Management System Manual (Annex IX of the Manual) comprises provisions related to the promotion of safety culture.

To implement the Policy on Safety Culture, an action plan has been prepared to improve in a systematic manner the culture for safety within CSN. A number of activities are conducted in CSN at all levels of the organization. At the time of the IRRS mission, the following actions were already implemented:

- Communication of the Policy to the staff;
- Integration of the Policy in the management system;
- Issuance of a procedure PA.XI.33 dealing with conflicts which may arise during decision making process.

Other activities were planned:

- Development of the knowledge management system process;
- Safety culture self-assessment;
- Training on safety culture for senior management and other organizational levels;
- Further development of graded approach to safety in CSN decisions and actions.

All the above-mentioned activities demonstrate a clear commitment of CSN to foster and strengthen the culture for safety of CSN.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Within CSN, UPEC is responsible for coordination and implementation of measurement, assessment and improvements activities of CSN. Several mechanisms are used by CSN to monitor, measure, and assess the management system and to confirm the ability of CSN to achieve its goals and identify opportunities for improvement of the management system. These include internal audits and periodic management system reviews.

The internal audits are coordinated by UPEC. About 28 CSN staff members have been trained as internal auditors. UPEC prepared a basic internal audit plan which is a part of the Management System Manual (Appendix IV). The basic audit plan sets up the frequencies of audits for all processes, usually one audit per process every 2 to 5 years. The frequencies have been decided on the basis of the significance and nature of the process activities. The basic audit plan covers also auditing of 9 Autonomous Communities that conduct inspections on the behalf of CSN. The audits planned for the following year are recorded as part of the CSN annual workplan. The activities related to the management system carried out by UPEC are not audited by CSN internal auditors but by contracted external organizations.

The management system review activities are defined in Management System Manual complemented by the procedure PA.XI.16 Review of the Management system. Twice a year, the Management System and Information Security Committee conducts a management system review. The review includes the assessment of opportunities for improvement and the need to make changes to the management system, including policies, goals and objectives.

Self-assessments are performed only at departmental and unit level. However, their scope is limited to the fulfilment of the objectives of the annual workplan and do not address the actual performance of the organization when conducting activities.

Corrective actions for eliminating non-conformities are determined and implemented. Their status and effectiveness are monitored and reported to the Management System and Information Security Committee. The management of non-conformances and corrective and preventive actions are defined in procedure PA.XI.01. CSN identified in the IRRS action plan that the process for control and implementation of

corrective actions and lessons learned derived from audits should be improved. The status and effectiveness of corrective actions are monitored. Due to the delays in solving non-conformities in 2015 an ad hoc working group was established to analyse the non-conformities and proposed improvement actions.

The minutes of Management System and Information Security Committee as well as the internal audits report are published on the Intranet and every CSN employee has access to them. The audits reports are discussed in the Agenda of the CSN Board meeting.

There has been no system in place to assess leadership for safety and safety culture. However, the Action Plan on CSN Safety Culture including independent assessment and self-assessment of leadership for safety and safety culture have been developed. However, the related activities are planned to be performed in 2019. Some activities from the action plan have been already implemented, such us:

- CSN collected information on safety culture assessment from other regulatory bodies abroad;
- The CSN Board approved one of suggested option on how to implement the safety culture self-assessment; it was decided that self-assessment will be implemented by engagement of an external organization;
- The external organization for supporting the safety culture is in process of selection.

This issue was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Self-assessment of the management system is limited to the evaluation of the implementation progress of the annual workplan.*	
(1)	**BASIS: GSR Part 2, Requirement 13 para 6.4 states that** *"Independent assessments and self-assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement. Lessons and any resulting significant changes shall be analyzed for their implications for safety."*
R5	**Recommendation: CSN should develop and implement provisions to conduct regular self-assessments of its management system.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although CSN has issued a comprehensive policy on safety culture, the system for assessments of leadership for safety and safety culture is not yet implemented.*	
(1)	**BASIS: GSR Part 2, Requirement 14 states that** *"Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization."*
S8	**Suggestion: CSN should consider conducting regular assessments of its safety culture.**

4.8. SUMMARY

CSN has established and implemented a process-based management system which integrates all functions and activities implemented by CSN. This system is to be updated to meet the new IAEA Safety Standard GSR Part 2 *Leadership and Management for Safety* closing the few gaps identified by CSN. The documentation of the management system is comprehensive, well organized and periodically reviewed. All management system documents are available on Intranet. However, the CSN has no system in place to self-assess the management system.

CSN has issued a Policy on Safety Culture and identified actions (including independent assessment and self-assessment of leadership for safety and safety culture) to foster safety culture within CSN. Several activities in the plan have been conducted to promote a culture for safety at all levels of the organization. The CSN action plan is underway.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The Spanish legal framework for the authorization system for facilities and activities was established under the provisions of Royal Decree 1836/1999 approving the regulation on nuclear and radioactive facilities. It is stated that authorization by the Ministry for the Ecological Transition, including specification of the conditions necessary for safety issued by the regulatory body in its mandatory report, are a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process. Royal Decree 1836/1999 provides criteria for determining which practices or sources are to be exempted from the requirements applying to nuclear facilities and radiation sources.

Using a graded approach, a similar authorization process applies to authorizations related to nuclear power plants, fuel cycle and radioactive waste management facilities and other nuclear and radioactive facilities. In addition to CSN, the main stakeholders that may be involved in authorization processes related to nuclear and radioactive facilities or activities are:

- Ministry for the Ecological Transition (MITECO) to which CSN issues the mandatory reports required to grant the licenses (see below);
- Government of the Spanish Autonomous Communities.

Two types of authorization exist, namely registration and licensing. Applications are submitted to the competent authority (ministry or regional government) which – in the licensing process - cannot grant any authorization before CSN issues a mandatory report which contains the results of CSN review of the safety assessment supporting the application. This report is binding for the competent authority in relation with safety, including when CSN concludes that the requested authorization cannot be granted. Thus, limits, conditions and controls established by the CSN report on the licensee's activities are annexed to the authorization.

Different types of authorizations have to be obtained for the different stages in the lifetime of nuclear facilities site authorization, construction and operating permits, design modification authorizations, decommissioning and closure. The set of documents that must be submitted depending on the types of authorizations and facilities is specified in Royal Decree 1836/1999. When deemed necessary, or as a result of regulatory actions such as inspections, reviews and assessments or feedback from operational performance, authorizations may be amended, suspended or revoked.

Applicants are required to submit an adequate and detailed demonstration of safety in support of their applications for authorization. At a general level, the scope and content of safety assessments are described in Royal Decree 1836/1999. Safety assessments are reviewed and assessed by CSN in accordance with specified procedures, following a graded approach.

In some cases, reviews are performed on the basis of regulations and standards developed in the country of origin of a specific facility (e.g., nuclear power plants).

CSN is in charge of granting authorizations for:

- personnel accreditation in nuclear and radiation source facilities (supervisors and operators, and "accreditation" to operate or command a facility of X-rays for radio diagnostic);
- license for Dosimetry Services, Radiation Protection Services and Radiation Protection Technical Units (UTPR). All licensees shall have an in-site Radiation Protection Service.

In accordance with a graded approach, registrants should have a contract with a Radiological Protection Technical Unit in order to provide them with specific support about radiation protection matters. Radiation

Protection Services and UTPRs are authorized by CSN. Heads of Radiation Protection Service must be recognized as such by CSN, which grants them a Certificate of Head for Radiation Protection.

The basis for regulatory decisions on the licensing of a facility or an activity is electronically recorded in the CSN computer information system, as well as in paper.

Administrative processes exist that allows the authorized party to appeal against a regulatory decision relating to an authorization for a facility or an activity or a condition attached to an authorization.

Provisions are in place to inform and consult interested parties and the public about the authorization processes and possible radiation risks associated with facilities and activities.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

Six pressurized water reactors and one boiling water reactor, located at five sites, are currently licensed to operate in Spain. On the other hand, one boiling water reactor which was commissioned in 1970 is currently shut down.

The authorization processes regarding nuclear power plants are described in Royal Decree 1836/1999. Specific authorization has to be requested for site authorization, construction permit, operating permit, modification permit, modification implementation, change of holder-ship, dismantling permit, and declaration of decommissioning. All authorizations are granted by the Ministry for the Ecological Transition on the basis of a CSN binding report. The set of documents that must be submitted depends on the type of authorization. A safety assessment must be included to applications for authorization related to nuclear reactors.

Guidance has been issued on the format and content of some of the documents to be submitted by the applicant in support of an application for an authorization: Radiation Protection Manual, On-site Emergency Plan, Organization Manual and Quality Assurance Manual. For the rest of the official documents, including the safety assessment, some guidance is available, but it is scattered. For instance, standard contents of the safety assessment developed in the country of origin of the design of nuclear power plant designs is used as a reference.

Independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body is performed for nuclear plants and nuclear facilities.

Regarding personnel authorizations, supervisors, operators and supervisors involved in fuel handling must be accredited by the CSN.

Design modifications of nuclear power plants may require authorization from the regulatory authorities before being implemented and commissioned, depending on their safety significance and following a graded approach.

Operating permits for nuclear power plants were granted for a 10-year period. Independently, periodic safety review has to be performed every 10 years. CSN Safety Guide GS-1.10 provides guidance on the scope and content of periodic safety reviews. This safety guide was revised in 2017 and is in line with IAEA Safety Guide SSG-25 on Periodic Safety Review for Nuclear Power Plants.

A comprehensive program for ensuring the long-term safe operation of nuclear power plants, addressing ageing management, has been established and is being implemented (CSN instruction IS 22). Although Spanish nuclear power reactors will reach their 40-year initial design life-time in the near future (between 2020 and 2027), the government has not made the decision to operate nuclear power plants beyond their initial design life-time. As a result, CSN recognized that addressing long-term operation of nuclear reactors, including planning for periodic safety reviews and license renewal reviews, represents a challenge to adequately position the required human and technical resources.

5.3. AUTHORIZATION OF FUEL CYCLE FACILITIES

Fuel cycle facilities require authorizations for site authorization, construction permit, operating permit, dismantling permit and declaration of decommissioning, or dismantling and closure permit and declaration of closure (the latter in case of facilities for the disposal of spent fuel and radioactive waste) and, where appropriate, authorization for design modification and change of holder-ship. The provisions related to the granting of these authorizations are those applicable to nuclear facilities, such as nuclear power plants, adapting the corresponding documents to the specific characteristics of such facilities.

Regarding Juzbado, CSN issued Complementary Technical Instructions (ITC) linked to the facility authorization that specifically requires the review of national regulatory provisions applicable including requirements formulated in foreign standards (e.g., by the US NRC) updates and changes on a yearly basis. The license holder (ENUSA) has thus to carry out an evaluation annually on any new standards and report to CSN.

The periodic safety review and license renewal processes applicable to nuclear power plants apply to nuclear fuel cycle facilities in Spain. The Juzbado fuel manufacturing facility was last authorized in 2016 – with a 10-year license. The periodic safety review was an integrated part of the license renewal.

A uranium mill facility (Retortillo, province of Salamanca) is under a licensing process. The site authorization was granted in 2015. The application for construction authorization was submitted in October 2016 and is currently under review. According to Royal Decree 1836/1999, this facility is classified as a Category 1 radioactive facility.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The El Cabril waste disposal facility is the main radioactive waste management facility currently in operation in Spain. It was originally designed to manage low-level and intermediate level-waste. A design modification was authorized to include very low-level radioactive waste disposal cells. The current operating permit was granted in 2001 and is valid until the full disposal capacity of the facility is reached. However, the licensee must provide an updated safety assessment every 10 years.

El Cabril authorizations cover Low- and Intermediate Level Waste (LILW) and Very Low-Level Waste (VLLW). Spanish's definition for LILW correspond to IAEA's definition of Low-Level Waste (LLW). El Cabril is also authorized for the storage of other radioactive waste, including some disused sealed sources, destined for future storage in the Centralized Spent Fuel Storage facility (CSF).

There is no time limit in the El Cabril license authorization. The facility is operated by ENRESA and is authorized for the disposal of 100 000 m3 LILW and 130 000 m3 VLLW, with limitations on the total activity content. The LILW repository have reached about 75% of its maximum capacity and could reach its maximum volume in the near term. The radiological content is covered for a longer time period. To ensure the continued availability of required disposal capacity, ENRESA plans to apply for a modification authorization, see also suggestion S1 in the ARTEMIS section of the report.

The life-span of the facility is divided into three phases: the operational phase, the monitoring phase (that should not last more than 300 years), and the release of the site from regulatory control. Each phase will be subject to a specific authorization.

An authorization will be needed for the closure. A plan for the institutional active control of the El Cabril facility over a maximum of 300 years will be required in the closure declaration. The transition period to a passive state will be defined in the authorization.

Art. 38bis of Law 25/1964, on nuclear energy, and Art. 4 of Royal Decree 102/2014, on the responsible and safe management of spent nuclear fuel and radioactive waste states that the State will take over the

responsibility spent nuclear fuel and radioactive waste once its disposal has occurred. It shall also assume the monitoring of the definitive disposal facilities after closure thereof. In addition, the State shall assume the surveillance that, in its case, could be required after the closure. This activity could be entrusted to ENRESA.

The authorization process for radioactive waste management facilities is the same as for the authorization of other nuclear facilities. The IRRS team noted that no specific guidance (format and content) of the documents related to the authorization process for radioactive waste management facilities, including safety assessments, is available. However, a CSN Safety Instruction on the scope and content of the safety demonstrations and studies at each stage of the life of surface disposal facilities for low level radioactive waste (LLW) is under development and should be approved in the next years. Guidance is also available regarding the long-term safety assessment for low- and intermediate-level waste surface disposal facilities.

Regarding the storage of spent nuclear fuel, additional storage capacity was needed in most of the nuclear power plants, so several individual storage facilities (ISF) were built and commissioned at NPP sites. From the regulatory standpoint, ISF are a part of the nuclear facilities constituted by the NPP and were authorized through the design modification authorization process. The storage casks are specifically licensed with 20-year authorizations.

A licensing process related to the building and commissioning of a centralized spent fuel temporary storage facility started in 2014. This process was temporarily stopped by the Spanish Government in July 2018. CSN review was nearly finalized after 4,5 years. The results will be preserved as a draft report, and the documentation of the process has been completed to allow the CSN to resume the review if necessary.

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

All new practices must be justified by its promoter before the competent authority, which, following the report from the CSN, decides whether its adoption is advisable. The legislation also gives provisions related to exemptions of practices or sources within practices to be exempted from requirements. Revision of justification of existing practices is foreseen in the legislation. However, GSR Part 3 para. 3.11. states that exemption shall not be granted for practices deemed to be not justified. This requirement is not covered in the regulatory framework, as discussed further in R6.

Optimisation of radiation protection is required in applicant documentation for authorization. In an application for registration optimization is set and verified by Radiation Protection Service (SPR) and Technical Unit of Radiological Protection (UTPR), while in an application for license optimisation it is included in safety assessment. A process for establishing dose constraints for practices subject of licensing is in place. Dose constraints related to non-medical imaging exposures are not given in Spanish legislation. This issue is covered in R6.

Current activity concentration levels for radionuclides used for exemptions levels are in line with levels given in Schedule I of the GSR Part 3, para. 3.10. Authorization issued by the regulatory authorities is required before the radiation source is acquired. The Spanish legal system does not contain provisions for notification of intention to operate a facility or to conduct an activity. However, as a rule, informal notification of regulatory body has been exercised for practices associated to higher risks. This issue is covered in R6. Two types of authorization exist, namely, registration and licensing.

Only a use of X-ray devices for medical purposes is a subject of registration. Autonomous Communities (ACs) or in a case of some specific ACs by MITECO are conducting registration process based on the documentation prepared by UTPR. Before starting the practice UTPR also visits the registrant site and makes a report. The IRRS team noted that CSN is not involved in registration processes however UTPRs are authorized by CSN. In 2017 a number of X-ray devices subject of registration was about 30 000.

Applicants for a license provide an application to MITECO or one of the ACs as appropriate. Three categories of facilities based on graded approach associated to the radiation risk are identified in Spanish legislation. Facilities of Category I are licensed by MITECO. All other facilities are a subject of licensing conducted by AC or in a case of some specific Communities by MITECO. According to the data of the CSN register of facilities, there were 2 facilities of Category I, 950 of Category II and 350 of Category III in 2017. A content of the application for a licence is given in Royal Decree 1836/1999, IS-28 and IS-40. CSN reviews and assesses applications and issues a report giving a position which is obligatory for the MITECO or ACs, as appropriate. According to the legislation a licensee should not start a practice without a special so-called "notification for start-up" issued by the CSN which is based on the CSN inspection visit of a licensee site.

The authorization duration is not limited in time. Provisions regarding revoking of a license are in place. Modification of an authorization is a subject of the same process as very first authorization, except in some specific cases. The CSN have a register of all issued registrations and licences containing also data of sources Category 1, 2, 3 and some Category 4 sources.

Spanish legislation uses a categorisation of sealed sources which is not fully in line with GSR Part 3 para. 3.56. The issue is addressed in R6. In licensing of an activity involving all sources of Category 1-3 financial provisions are required from the applicant to assure safe management of radioactive source.

The requirements for regulatory control of a use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research also called non-medical imaging have not been fully established in current Spanish legislation. Namely, Art. 7 of the Royal Decree 815/2001, on the justification of the use of ionizing radiation for the radiation protection of people subject to medical exposures refers only to a use of medical equipment in so-called medico-legal exposures. The issue is addressed in R6.

Current Spanish legislation does not contain provisions regarding sealed or unsealed sources which are contained in deceased persons or human remains, either as a result of radiological procedures for medical treatment of patients or as a consequence of an emergency. This issue was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission. The issue is addressed in R6.

The import and export of radioactive sources is a subject of regulation based on IAEA Guidance on the Import and Export of Radioactive Sources and Code of Conduct on the Safety and Security of Radioactive Sources. CSN is the point of contact as well as ACs. The consent for the import is given by AC or MITECO when applicable. For the export already mentioned IAEA Guidance is followed. The point of contact is CSN. All suppliers of sealed sources must submit to CSN a quarterly report of sources they have supplied and to whom. The IRRS team was informed that CSN does not directly engage with Customs regarding the import of the sources.

Today all sources except sources produced in cyclotron are imported in Spain. A part of the application for a license is a contract between a supplier and a user stating that the supplier is going to take the source back at the end of its working life. When reuse of source is not possible the owner should deliver it to ENRESA whenever it cannot be returned to the manufacturer.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *While the Spanish legal and regulatory framework provides a basis for the authorization of radiation sources facilities and activities there are gaps in its coverage, including:* *1) exemptions are not to be granted for practices deemed to be not justified;* *2) the provision for submission of a notification of an intent to operate a facility or to conduct an activity, consistent with a graded approach;* *3) categorisation of sealed sources is not fully in line with the required categorization scheme.*	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."*
(2)	**BASIS: GSR Part 3 Requirement 6 states that** *"The application of the requirements of these Standards, i.e. GSR Part 3, in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures."*
R6	**Recommendation: The Government should revise the legal and regulatory framework to comply with the requirements of GSR Part 3 for strengthening the control over radiation sources facilities and activities.**

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Regarding decommissioning, Spain has:

- established a clear policy with respect to radioactive waste management and decommissioning (via approval of the GRWP);
- installed a legal, regulatory and organizational framework with clear allocation of responsibilities of all parties involved in radioactive Waste and Spent Nuclear Fuel Management and decommissioning of facilities, and applies a graded approach in licensing such activities;
- the availability of a substantial infrastructure for the management of radioactive waste, comprising a suit of interdependent radioactive waste processing installations;
- on-site storage facilities available for Spent nuclear fuel (SNF), awaiting construction and operation of a centralized storage facility for High Level Waste (HLW) and SNF;
- a disposal facility for Low and Intermediate Level Waste as well as for Very Low-Level Waste;
- the technology and knowledge available for the dismantling of facilities and remediation of contaminated areas;
- a system for building up funds to guarantee radioactive waste management and decommissioning activities;
- clearance levels available.

This allows for decommissioning and remediation activities to be safely and continuously carried out in a timely manner and in compliance with national legislation, international conventions and IAEA standards.

The dismantling permit lists conditions establishing what information or reports must be sent periodically to CSN: operating experience, design modifications, training programs, environmental radiation monitoring programs results, staff dosimetry, radioactive waste activities, operating life management activities, etc.

The current General Radioactive Waste Plan (GRWP) considers as baseline scenario the immediate and complete decommissioning of light water nuclear power plants (NPP) to be commenced three years after their final shut-down. Only the deferred dismantling of the gas-cooled reactor of Vandellós I nuclear power plant is exceptionally considered. This strategy was chosen because of the inherent difficulties in the management of the graphite used as moderator.

At present two NPP are subject of dismantling:

- José Cabrera NPP: decommissioning and dismantling activities by ENRESA started in 2010. Present activities focus on the decontamination of the building structures and on the site restoration with removal of contaminated grounds. Dry storage of Spent Fuel is organized on site.
- Vandellós I NPP: a gas-cooled (CO2) natural uranium graphite nuclear power plant, operational till 1989. Its partial dismantling by ENRESA started in 1998. At present, the plant, partially dismantled and in a safe condition, is being maintained in a state of dormancy for a period of 25 years under monitoring and control. This dormancy period started in 2005. All activities associated with it are covered by the GRWP Fund. After the decay period the concrete reactor vessel and the rest of the facility's structures will be dismantled and removed, in order to release all the lands inside the site.

Moreover, a number of uranium concentrates manufacturing plants are either waiting for a dismantling license, are dismantled or are in a long-term surveillance or compliance phase. Closed uranium mines in the Autonomous Communities of Extremadura, Andalucía and Castilla y León, were restored. Two research reactors have been decommissioned and the Integrated Plan for the Improvement of CIEMAT Facilities (PIMIC), implying dismantling and remediation activities, is in progress.

The granting of the dismantling license for nuclear facilities and nuclear fuel cycle radioactive facilities is preceded by the declaration of shutdown by MITECO, specifying the conditions applicable to the activities to be performed in the period between shutdown and the grant of the dismantling license. The transfer of responsibility to ENRESA (in charge of the decommissioning and dismantling of nuclear facilities) is done at the same time as granting the dismantling permit. After shutdown of operation, and prior to granting the dismantling license, the licensee has to condition the operational wastes and unload the spent fuel from the facilities (art. 28 of the Royal Decree 1836/1999) or has a spent fuel management plan approved by MITECO.

Dismantling and decommissioning of radioactive facilities are covered by the operation license that is granted by the Directorate General for Energy Policy and Mines. The licensees of such facilities are responsible for their dismantling and decommissioning.

During discussions regarding the transfer of responsibility of José Cabrera NPP to ENRESA, the IRRS team was informed that no compulsory requirements are available in present regulations with respect to retaining key staff, nor concerning the transfer to ENRESA of all information on the facility ("institutional knowledge") that is important for the safe and secure dismantling of it. However, CSN Safety Guide 10.13 mentions that prior to the transfer of responsibility all the documentation regarding the facility should be transferred. This Safety Guide is non-binding. Such institutional knowledge would normally include details regarding operational incidents and accidents that resulted in a spread of contamination within plant structures, systems and components, as well as in its environment. Actions that have been undertaken to remediate the problem should also be described. However, in the case of the transfer of responsibility from the licensee (GAS NATURAL FENOSA) to ENRESA, CSN asked legal advice in order to facilitate the transfer of key staff (licensed operators and supervisors) to the new operator. The advice of the legal

department made it possible that the licensed operators and supervisors from the NPP were taken over by ENRESA.

CSN will modify the existing draft Instruction on "basic requirements for the safe decommissioning of nuclear facilities that are applicable during the design, construction and operation phases" in order to cover the obligation of transfer of information.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *CSN instruction IS-26 §8.3 states that all relevant information from the installation's design, construction and operation stages that might make the subsequent decommissioning activities easier must be recorded and kept. However, with respect to transfer of knowledge and of information about the facility important to nuclear safety and radiation protection, only the non-binding safety guide 10.13., is available and deals with such transfer in case of transfer of responsibility for the facility to ENRESA (for decommissioning).*	
(1)	**BASIS: GSR Part 6 Requirement 7 (Integrated management system for decommissioning), para. 4.4 states that** *"Individuals performing decommissioning actions shall have the necessary skills, expertise and training to perform decommissioning safely. Provisions shall be made to ensure that institutional knowledge about the facility is obtained and made accessible and, as far as possible, that key staff from the facility are retained."*
S9	**Suggestion: CSN should consider establishing regulatory provisions requiring the authorized parties, as a prerequisite for the transfer of responsibility of the facility, to ensure the transmission of institutional knowledge.**

The disposal, recycling or reuse of radioactive substances or of materials containing radioactive substances from any nuclear or radioactive facility shall be subject to authorization by the Directorate General for Energy Policy and Mines, following a report by the Nuclear Safety Council.

Criteria for the release of sites and criteria for the radiological control of residual materials generated in nuclear facilities are given in Instructions IS-13 and in the ministerial order ETU/1185/2017 of 21 November 2017 (and IS-31) respectively (see also 5.10). It's up to the licensee to propose and justify a set of release levels in accordance with the radiological criteria and with the site's planned end use, as well as the methodology used to perform the final radiological characterization of the site, in order to demonstrate that all established radiological criteria are met. IS-31 defines also the technical documentation that must be submitted to support the application for a clearance authorization.

When dismantling activities are accomplished a declaration of decommissioning will be issued by MITECO, declaring the site released or putting restrictions on the future use of the site and mentioning the body responsible for maintaining and verifying compliance with the restrictions. CSN is charged with the verification of the demonstration of compliance with end state established by the licensee. The IRRS team was informed that, although a verification of end state is performed, the present regulations do not impose the establishment of a final decommissioning report in the sense of the IAEA standards. Such document should, besides the description of the work performed and the type and amounts of waste generated or materials cleared, comprises the (updated) information mentioned in the site restoration plan making part

of the decommissioning license application. At present the making of such final decommissioning report is taken up in the draft regulation instruction "the safe decommissioning, and where appropriate, safe closure of nuclear and radioactive fuel cycle facilities".

Safety report Series 45 on standard format and content for safety related decommissioning documents, describes in chapter 4.7. the composition of a decommissioning report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The current statute requires CSN to verify the completion of the dismantling activities, however, current regulations do not require authorized parties to submit a final decommissioning report as part of the application file for license termination.*	
(1)	**BASIS: GSR Part 6 Requirement 15, para. 9.1 states that** *"A final decommissioning report shall be prepared by the licensee to demonstrate that the end state of the facility as specified in the approved final decommissioning plan has been reached. This report shall be submitted to the regulatory body for review and approval."*
S10	**Suggestion: CSN should consider updating the regulatory provisions to add a requirement for licensees to submit a final decommissioning report as part of the application for license termination, including a description of the contents of the final decommissioning report.**

5.7. AUTHORIZATION OF TRANSPORT

More than 100 000 packages are transported each year in Spain by road, air and sea (rail transport is not used at present). The majority of the transports (near 70%) is involved in the medical sector, using mainly Excepted and Type A packages transported by road. Around 20% of the transports takes place in the industrial sector (industrial radioactive facilities). They involve mainly Excepted packages, Type A packages and Type B packages. Most of them are transported by road.

Less than the 10 % of the transports are conducted in the nuclear sector. They include:

- Concentrates of uranium in Industrial Packages. About 10 transit shipments per year by sea.
- Fresh Nuclear Fuel (non-irradiated, UO_2 powder, fuel elements) in Type IF and Type AF packages. About 70 shipments per year by sea and road.
- Irradiated Nuclear Material (fuel rods, activated samples) in Type B(U)F packages. Some shipments from Spanish nuclear power plants to European research facilities by road and sea.
- Contaminated objects: about 100 shipments at a year from/to nuclear facilities, using mainly road transport.
- Radioactive waste from nuclear facilities mainly in Industrial packages. About 300 shipments per year mainly by road transport.

Currently, there are no shipments of spent nuclear fuel. They are expected when the Nuclear Spent Fuel Temporary Storage Facility (CSF) is licensed.

All the shipments described above are subject to the requirements of the IAEA Transport Regulations SSR-6 which are fully implemented in Spain. In particular all approval requirements of the IAEA Transport

Regulation SSR-6 (para. 802, "approval" is used in SSR-6 instead of "authorization") are included in the international modal Regulations in force for each mode of transport (ADR, RID, IMDG code and the ICAO Technical Instructions) whose compliance is required in Spain. These modal Regulations are integrated into the national legal framework through the requirement of their use by specific Royal Decrees. However, currently not all approval needs of SSR-6 are assigned to the competent authority under Article 77 of Royal Decree 1836/1999 (para. 802 (a)(ii), (d), (e) and (f) of SSR-6 are missing). This non-compliance was identified in the Advance Reference Material (ARM) based on the self-assessment and is stated as a recommendation (R37) and an action (A37) in the updated CSN Action Plan. This recommendation and associated corrective action are confirmed and strongly supported.

In addition, it was found that the implementation of the notification requirement of para. 557 of SSR-6 regarding the first shipment of an approved package design is not assigned to CSN as the competent authority to be notified nor to any other authority. To close this gap, it is proposed to extent the revision of Article 77 to include also the notification requirement according to SSR-6, para 557 in such a way that this notification shall be submitted to a competent authority (CSN and/or any other authority).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *While the Spanish legal framework contains provisions for approval responsibilities, there are gaps in its coverage regarding approval for designs of low dispersible radioactive material, radiation protection programme for special use vessels, calculation of unlisted radionuclide values and calculation of alternative activity limits for an exempt consignment of instruments and articles. In addition, neither CSN nor any other authority is designated to receive the required notification for the first shipment of any package requiring competent authority approval.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 2, para. 2.5. (3) states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:…(3) The type of authorization that is required for the operation of facilities and conduct of activities,…."*
(2)	**BASIS: SSR-6, para. 802 states that** *"Competent authority approval shall be required for the following: (a)(ii) Designs for low dispersible radioactive material, …. (d) Radiation protection programme for special use vessels, (e) Calculation of radionuclide values that are not listed in Table 2, (f) Calculation of alternative activity limits for an exempt consignment of instruments or articles.*
(3)	**BASIS: SSR-6, para. 557 states that** *"Before the first shipment of any package requiring competent authority approval, the consignor shall ensure that copies of each applicable competent authority certificate applying to that package design have been submitted to the competent authority of the country of origin and each country through or into which the consignment is to be transported."*
R7	**Recommendation: The Government should assign the responsibility for all approval types according to the IAEA Transport Regulations and identify the competent authority for notification regarding the first shipment of an approved package in Spain.**

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

Requirements on supporting documents regarding occupational protection for authorization requests.

Authorization requests of nuclear facilities, nuclear fuel cycle radioactive facilities and first category radioactive facilities must be supported by a Radiation Protection Manual. This document provides among other the requirements concerning the radiation protection issues related with the installation of concerns: radiation protection programme, implementation of the optimization principle, monitoring of the workers.

For the radioactive facilities of second and third category, the same document is mandatory as a part of the operating regulation requested in Royal Decree 1836/1999 and the Safety Guides GS 5.1 (rev.1) and GS 5.2 (rev.1).

Requirements to ensure that protection and safety is justified and optimized for occupational exposure.

Art. 4 of Royal Decree 783/2001 on Regulation on Sanitary Protection against Ionising Radiations requires that *"All new class or type of practice included within the scope of this present regulations must be justified by its promotor before the competent authority which following the report of the CSN, shall decide whether its adoption is advisable, considering the advantages that it may represent in relation to the potential damage that it may cause to health. The CSN may propose the revision of the existing classes or type of practices from the point of view of their justification, whenever new or important evidence appears regarding their efficiency or consequences."*

Art. 3.2 of Royal Decree 783/2001 requires the implementation of the optimisation principle. In art.6 of the same Royal Decree, the obligation for the title-holder to use, when appropriate, dose restrictions in the context of the optimization is provided. Such dose restrictions shall be evaluated, and if fitting, shall be approved by CSN.

Requirements on dose limits and dose constraints.

Dose limits for the occupationally exposed workers are defined in Royal Decree 783/2001, art. 4.3 and art.9 respectively. The limits are complying with IAEA's Standards except for the lens of the eyes as stated in Royal Decree 783/2001 art.9.2. a) and art.11.2. a).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although limits for occupationally workers are defined in the Spanish regulations, the limits for the lens of the eyes for the occupationally workers and for students and trainees between 16 and 18 years old do not comply with the required standards as described in Schedule III of the GSR Part 3.*	
(1)	**BASIS: GSR Part 3 Requirement 12, para.3.26 states that** *"The government or the regulatory body shall establish dose limits for occupational exposure and public exposure, and registrants and licensees shall apply these limits"*
R8	**Recommendation: The Government should update the dose limits for the lens of the eyes to ensure full compliance with the IAEA Safety Standards.**

Requirements and responsibilities for the protection of workers in planned and existing exposure situations.

Responsibility of employers, registrants and licensees is indicated in Art. 7 of Royal Decree 783/2001, "The title-holder of the practice shall be responsible for the compliance and application of all the principles herein established, within the scope of the activity and competence".

Cooperation of employers and registrants/licensees.

Royal Decree 413/1997, Art. 4 states that "The external company shall be responsible for the radiological protection of its workers, in application of what is established in the Royal Decree 783/2001". Moreover, Art.6 requires that all off-site workers are obliged to collaborate with those responsible for radiological protection, both those of their own company and those of the licensee of the facility, in their protection against ionising radiations, fulfilling the standards established by them.

The cooperation at the level of both employers, the one of the hosting facility and the one of the external company, is supported by the need for complying with requirements related to the implementation of the safety and radiation protection measures taken by the hosting company (Royal Decree 413/1997, Art 5) and which are, for example, part of the ALARA procedure to be fulfilled before the beginning of the works, the radiological work permit, the monitoring of the workers and as being registered in the national register for external companies.

Organizational, procedural and technical arrangements regarding designated areas and monitoring of workplaces.

These arrangements are described in the Radiation Protection Manual specific to each nuclear installation and radiological installation and which is part of the request for authorization of these installations. The expert was provided with the table of content of a RP Manual as described in SG.7.06 which contains, among others, the main arrangements concerning the definition of areas, the monitoring of the workplace, the training required and the optimisation programme.

Information, instruction and training

Art. 21,1. of Royal Decree 783/2001 requires that "the title-holder of a practice or, when applicable, the external company, must inform the exposed workers, persons in training and students that during the course of their studies must use sources, before initiating activities, about:

- the associated radiological risks and the importance of fulfilling the technical, medical and administrative requirements;
- the norms and procedures for radiological protection, as well as the precautions that must be taken, as regards the practice in general, and each type of position or job that mat be assigned to them.

Royal Decree 783/2001, Art.21.2., requires that "The title-holder of the practice or, in its case, the external company, must provide the exposed workers, the persons in training, and the students, before they initiate their activity, and periodically, training in matters of radiological protection, to a level that is adequate with their responsibility and the exposure risk to ionizing radiations in their workplace".

Requirements on special arrangements for protection and safety of female workers and for persons under 18.

Special arrangements for protection and safety of female workers.

Art.21.1.c) of Royal Decree 783/2001 requires that*" In case of women, the need to inform as soon as possible about the condition of pregnancy and lactation, taking into account the exposure risks for the foetus, as well as the risk of contamination of the child in case of corporal radioactive contamination".*

Art.10 of Royal Decree 783/2001 states the requirements for the special protection during pregnancy and lactation. Moreover, Royal Decree 783/2001 art. 64 prescribes that in the radiation protection programme for the exposure of the aircraft crew, the application of this art. 10 must be taken into consideration. These regulations are compliant with the relevant IAEA requirements.

Dose limits for students and trainees.

The dose limits for persons in training and students are described in Royal Decree 783/2001 art. 11 and are compliant with the IAEA's Standards excepted for the limit of the lens of the eyes (see recommendation R8).

Specially authorised exposures.

Specially authorized exposures are addressed in Royal Decree 783/2001 Art.12.2. b. For this exposure, CSN will define the specific dose limit for each case.

Radiological Protection Service (RPS) - Radiological Protection Technical Unit (UTPR)

RPS and UTPR must be authorised by the CSN. The tasks allowed to such services and units, such as control of individual dosimetry, are indicated in CSN's Safety Guide 7.03, Revision 1. These services or technical units are composed of a Head and experts and technicians in the field of radiological protection. Heads of these services and units are qualified experts in radiological protection.

In the CSN's Safety Instruction IS-03, the qualifications required to obtain recognition as an expert in protection against ionizing radiations are laid down regarding the minimum training and experience that the CSN considers necessary for the candidates, both for the persons responsible for the Service or Unit, as for the technical staff at their charge.

Exposure records.

The need for - and the duration of - the maintenance of exposure records is addressed in Royal Decree 783/2001, art. 34 and 38. This information must be made available for the CSN and to the workers when appropriate.

5.9. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

The responsibilities for healthcare and regulatory control of medical exposures are distributed among the following organizations: Competent Autonomous Community Authority of Industry, Competent Autonomous Community Authority of Health and Nuclear Safety Council (CSN).

According to Royal Decree 1836/1999 and Royal Decree 1085/2009, the respective users from radioactive facilities and facilities using X-ray equipment for medical diagnosis shall present an application for authorization either for a license or for a registration. License is issued by MITECO or ACs based on perceptive and binding report of the CSN regarding the radiological protection of workers professionally exposed, the public and the environment. CSN's Instruction IS-28 on the technical specifications that second- and third-Category radioactive facilities must observe, sets specific requirements for medical radiation facilities. For the use of X-ray equipment for medical diagnosis registration is required based on the report of the Radiological Protection Technical Unit UTPR regarding the radiological protection of workers professionally exposed, the public and the environment. These authorisation processes do not take into account radiation protection of patients. This is covered in R1 in Module 1.

The authorization of suppliers is regulated by Art. 74 of the Royal Decree 1836/1999 for radioactive facilities and by Art. 9 of the Royal Decree 1085/2009 for facilities using X-ray equipment for medical diagnosis. In all cases the authorization of the suppliers is issued by the Competent Autonomous Community Authority of Industry based on the perceptive and binding report of the CSN.

5.10. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

The addition of radioactive substances to consumer goods and the import, export or movement within the European Union (EU) community, is regulated by Royal Decree 1836/1999 and Royal Decree 783/2001. The introduction into the Spanish market of consumer products that incorporate radioactive substances, even if their use is included in the exemptions foreseen in Appendix I of Royal Decree 1836/1999, requires authorization from the Directorate-General for Energy Policy and Mines, following a report from the CSN.

According to art. 51 of Royal Decree 783/2001, all discharges of effluents and solid radioactive waste into the environment requires the authorization of MITECO. Such authorization includes discharge limits and surveillance requirements, conditions for releases and for protection of the members of the public.

Dose limits for the public are established in art. 13 of Royal Decree 783/2001. The effective dose constraint for nuclear facilities and for radioactive facilities of the nuclear fuel cycle is set at 0.3 mSv/y.

Operators are required to monitor discharges of radionuclides into the environment. The discharge limit for nuclear facilities set at 0.1 mSv/y over 12 consecutive months for each unit on site and is specified in the operating license as part of the Plant Performance Technical Specifications. It applies to all emitted radioactive effluents and is valid for operation and decommissioning phases. For the El Cabril waste disposal facility there is a zero-discharge criterion for liquid effluents and an effective dose criterion of 0.01 mSv/y for gaseous discharges. The Joint Convention Report of Spain (2018) mentioned that discharges approach 4 % of the limit for NPP and around 8 % for El Cabril.

CSN's Safety Instruction IS-28 on the technical specifications that second- and third-Category radioactive facilities must observe, sets specific requirements for radioactive facilities. The operation license may contain limits for controlled discharges of liquid radioactive effluents into the public sewer system.

Criteria for the release of sites of nuclear facilities and criteria for the radiological control of residual materials generated in nuclear facilities are given in CSN's Safety Instructions IS-13 and IS-31 respectively (see also 5.6).

5.11. SUMMARY

Royal Decree 1836/1999 provides the legal framework requiring licensees to conduct safety assessment for each authorization stage of regulated facilities and activities, and under which the CSN conducts its review and assessment on the licensees' applications before authorization. This legal framework is well developed and implemented and includes consideration of a graded approach. This framework is, in general, in line with IAEA safety standards.

However, areas for improvement in the authorization process were identified and include:

- the justification of exempted practices;
- the notification system for facilities and activities;
- the sealed sources categorization scheme;
- the transfer of institutional knowledge about facilities to the entity in charge of dismantling and decommissioning activities;
- the content of the final decommissioning report;
- the assignment of responsibilities for all approval types and for notification (transport);

- the dose limits for the lens of the eyes.

The IRRS team recognized that the CSN conducted a thorough self-assessment regarding the legal and organizational details related to authorizations of nuclear and radioactive facilities and activities.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

CSN performs review and assessment of licensing submissions received from all nuclear installations, other fuel cycle facilities and facilities using radiation sources, the manufacturing of apparatus, and equipment or accessories generating ionizing radiations seeking a particular authorization to determine whether the applicant complies with applicable regulatory requirements. The Spanish legislative and regulatory framework establishes the CSN responsibility of review and assessment during all stages of the authorization process, from operation until closure in order to ensure that the facility does not pose unnecessary risk to the people and the environment. The review and assessment process of the technical documentation attached to the different applications and the continued review and assessment during operation and decommissioning or closure are commensurate with the nature and potential magnitude of the associated hazards.

In pursuance of the legislative and regulatory framework, the applications for authorization are addressed to the competent Ministry, which provides a copy of all the documentation to CSN for the preparation of its mandatory evaluation report based on the results of the review and assessment. CSN reports for the granting of authorizations are mandatory in all cases and binding if negative, or if the report is positive, binding in the safety-related conditions imposed.

The regulatory framework establishes the type of authorizations required for different types of facilities. It also specifies what is authorized by each type of authorizations, the documentation to be submitted with each application, and the corresponding administrative process. A graded approach is followed in relation to the documentation to be submitted with each application, depending on the type of nuclear or radioactive installation.

The management procedure for review and assessment includes guidance to cope with deficiencies in the information identified during the assessment process. During the assessment process, information content is analysed in two stages. In the first stage, the formal content of the application is verified against the established quality criteria. If the documentation is found to be unacceptable, the applicant has the chance to improve the proposal by rectifying the deficiencies. Otherwise, the application can be rejected. In the second stage, the documentation is properly assessed, with an analysis of the technical sufficiency and justification.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

CSN employs a sufficient number of qualified and competent staff, commensurate with the nature and number of facilities and activities to be regulated, to carry out its functions and responsibilities in review and assessment. Core competence in review and assessment is ensured through regular training of CSN staff, participation in activities of international organizations and participation in research and development activities.

The knowledge and capabilities required for review and assessment in different technical areas are part of the CSN training program that is annually updated. Additionally, the regulatory body has adequate arrangements for obtaining technical or other expert professional advice or services in support of its regulatory functions, such as review and assessment. There are different ways in which the CSN may obtain technical advice or support, from technical advisory commissions to contracting technical services.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

CSN performs review and assessment to verify licensee compliance with the applicable regulations and the acceptance criteria established in regulations as well as applicable CSN safety instructions, safety guides and technical procedures which form the licensing basis of the assessment. These documents specify the technical basis for the assessment and the acceptance criteria of the submitted documentation.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

CSN has developed several management procedures as described in sub-section 6.1.1 and above that provide detailed guidelines on the process for review and assessment of different facilities and activities and guidelines for report preparation by CSN. When dealing with a particularly significant, large or new application for which there is no specific procedure, guidance on how to perform the assessment is prepared including the most significant issues relating to nuclear and radiation safety that must be assessed for grant of an authorization. The CSN keeps a complete record of all documentation associated to its assessments and reviews that is stored in a centralised database where it is kept safely and easily accessible.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

For NPPs, the types of authorisation established in the Spanish regulatory framework are: site, construction, operation, modifications in design and technical specifications, decommissioning, temporary storage of nuclear substances and change of licence holder. The licensing basis is the set of regulations including CSN instructions, conditions and commitments to which the validity of the concerned authorisation is linked and constitutes the reference framework against which the review and assessment process is conducted. The licensee has to demonstrate compliance with the said licensing basis. The licensing basis is reflected in the limits and conditions of the specific licence (including, when applicable, the regulations of the country of origin of the technology) as well as in the official operation documents, which are referenced on the licence. The CSN or the competent ministry, according to their responsibilities, can modify said licensing basis; in addition, the CSN can setup detailed requirements by issuing legally binding Complementary Technical Instructions (ITC).

Regarding integrated safety assessment by combining the results of the review and assessment, inspections and operating performance of the facility at regular intervals, it was explained that besides the 10-year review Periodic Safety Review (PSR), CSN performs a global assessment every year (and each quarter of the year, in lower detail) of nuclear power plants considering the following aspects:

- Number and importance of Inspection findings and Inspection crosscutting components
- Results of the SISC (Integrated Supervision System of NPPs) performance indicators
- Significant aspects of the review & assessment process (evaluations) including the reported evaluation deficiencies which identify the shortcomings in the quality of the proposals submitted by the licensee for CSN evaluation before acquiring an authorization.

CSN further informed that according to its internal working procedure PG.IV.07, although the aspects pointed out above were tracked individually, CSN conclusions were obtained on the basis of a global assessment of the licensee's performance. The results of these plant assessments were included in an annual report and conclusions were shared with the licensee; first, through a formal letter to this particular installation, and later these were directly explained to the licensee during the annual meeting held in the relevant installation.

Regarding the competency of its technical staff in different areas involved in the review and assessment process, CSN explained that it possesses sufficient and competent technical staff able to cope with the activities that are being performed currently with regards to the review and assessment. However, on need

basis, the corresponding directorate may ask the competent authority to seek external expert support for a specific task requiring technical assistance. In addition, the training program was informed to be flexible enough to accommodate for specific training of the staff in emerging areas.

Nevertheless, CSN faces a real challenge to maintain in future, the cumulative knowledge (knowledge management) taking into account pertaining to deterministic and probabilistic safety analysis by using analytical computer codes for the purpose of performing selective audit or confirmation of the analysis presented by the licensee in safety documentation/analysis reports to support the regulatory review process.

CSN informed that in accordance with PG.IV.08 rev.2, Paragraph 2 it possesses the capacity to perform different types of independent audit analysis in order to verify the adequacy of the analysis presented by the licensees. In order to perform these calculations, the CSN relies upon its available technical capabilities and also on external supports from organizations like the Spanish universities or CIEMAT (national research centre) which has different groups related to nuclear energy and radiological protection.

CSN also uses PSA methodology for risk informed decision making while reviewing and assessing design modifications, analysis of operational events, and prioritizing inspections etc. CSN informed that it utilizes PSA models and methodologies for different aspects such as:

- Risk informed evaluation: CSN Safety Guide 1.14 contains the guidelines to apply these methodologies. This guide is based on USNRC Regulatory Guide 1.174. The initiative is on the licensee side (there has not been new proposals since the early 2000´s).
- Inspection planning: the more risk significant a system, structure and component is the more frequently it is inspected.
- Inspection findings categorization.
- Precursor analysis for "reactive inspection" decision making.
- Indicators (SISC).

CSN informed that it has been using the licensee PSA models for more than 15 years for performing PSA confirmatory calculations. However, in 2015-2016 a feasibility project was performed to assess CSN ability to develop and use regulator's models and in 2017 a new project was started to develop standard regulator's models which is ongoing as of today, with the NRC support.

CSN has a system of categorization of findings of review and assessment with regards to safety significance of the deficiency identified. CSN informed that it closely follows licensees' implementation schedule for fulfilment of various safety improvements. The task is currently assigned to the project managers who have their own methods to control this issue. However, just before the IRRS process it was decided to develop a corporative method (and the corresponding computer tool) to have a common approach to this important management aspect. This tool has been incorporated in the Action Plan and will be fully implemented in 2019.

6.3. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

The fuel fabrication facility in Juzbado (Salamanca) has been in operation since 1985. The operator, ENUSA, manufactures fuel assemblies from imported enriched uranium oxide powder and gadolinium oxide. No chemical processes are conducted in the facility. Individual spent fuel dry temporary storage facilities (ISF´s) are located at the Trillo, José Cabrera and Ascó nuclear power plants. The Almaraz and Santa María de Garoña plants recently received their licence and Cofrentes is currently in the process of licensing an ISF.

Provisions are in place for CSN to perform review and assess information submitted by the operating organizations of fuel cycle facilities. The general approach for conducting the review and assessment of the applications presented to obtain an authorization is the same for FCF than for NPPs and other practices

involving radioactive material. The CSN safety guides recommend the content of the documentation to be submitted by the operating organizations of the FCF, which must be evaluated and approved. The CSN has a set of Management (PG) and Technical (PT) procedures available applying to the assessment process. Some of them are applied in a general or specific way to the FCF. Examples of these procedures are listed in the answers to SARIS questionnaire.

Chapters III (Art. 17e) and IV (Art. 20a) of RD 1836/1999 defines the required contents of the Preliminary Safety Analysis Report required for a construction permit and the Safety Analysis Report required for an operating permit, respectively. The draft decree on nuclear safety in nuclear facilities pending Government approval and the CSN instruction IS-26 establishes the scope and objectives of the Safety Analysis Report. Article 12 "Safety Assessment" of the draft decree establishes that the licensee must carry out an evaluation of the installation (site, design and operation) to determine that an adequate level of nuclear safety has been reached and that the installation meets the safety objectives (of Article 6).

According to the Royal Decree 1836/1999, the Safety Analysis Report required to obtain an operation license shall include an evaluation of risks arising from the operation of the installation, both in normal and accident conditions. The analysis shall result in Performance Technical Specifications (ETFs) establishing the safety functions of the different systems, the limit conditions for these functions to be fulfilled, and the tests and verifications that must be carried out.

Article 13 "Periodic safety review" of the draft decree establishes that the licensee systematically and periodically shall re-evaluate the nuclear safety of the facility at least once every ten years. The CSN instruction IS-26 establishes that every ten years at the most, the licensee of the nuclear installation must conduct and document a periodic safety review (PSR), the goal of which will be to make an overall assessment of the behaviour of the installation during the considered period by means of a systematic analysis of all nuclear safety and radiological protection aspects. Particular CSN Technical Instructions on periodic safety reviews are issued for fuel cycle facilities.

Furthermore, Article 8 of the CSN instruction IS-19 specifies that operating organisations of fuel cycle facilities shall perform systematic safety assessments of the facility at regular intervals throughout its operating lifetime, with due account taken of operating experience and significant new safety related information from all relevant sources, including international standards and operating experience.

In July 2012 the CSN issued the Juzbado fuel fabrication facility with a Complementary Technical Instruction requiring the implementation of improvement measures identified during the stress test required following the Fukushima Daiichi accident. The first evaluation resulted in an ITC to perform additional analyses on earthquakes, flooding, loss of electric supply, control room, accident management, etc. Also, requirement to implement certain safety improvements, e.g. including a bunkered control room for improved security and emergency preparedness, etc. A final report issued by CSN on 5th October 2018 summarizes all improvements and actions and closes the issue.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The specific process for reviews and assessments is developed in detail in management procedure PG.IV.08, applicable also for radioactive waste management facilities.

The management of radioactive waste, including spent fuel, and the dismantling and decommissioning of nuclear facilities is addressed in Chapter VI Articles 38 and 38bis of the Nuclear Energy Act (Law 25/1964). The Royal Decree 102/2014 for the responsible and safe management of spent fuel and radioactive waste further develops the regulatory framework on a strategic and policy level, covering waste and spent fuel from generation to disposal.

The process for the approval of the 7th General Radioactive Waste Plan (GRWP) has not been started, see module 1, so the Plan has not been sent to CSN for review. The CSN expect to review the plan from a technical and safety perspective, with a binding recommendation to the Government. The CSN expect to be well prepared for the review but there is no developed strategy or procedure with criteria for the review.

ENRESA´s documented procedures for waste acceptance enable CSN to review and assess in more specific technical detail with respect to the general requirements on waste acceptance criteria contained in the El Cabril authorization. The regulations for processing of radioactive waste consider the characteristics of the waste and of the demands imposed by the different steps in its management. The processing and interim storage of LLW and VLLW generated in the nuclear facilities adhere to the waste acceptance criteria of the El Cabril disposal facility operated by ENRESA. Control of the processing and storage of radioactive waste is conducted by CSN through the licensing and supervision of treatment and conditioning systems in the nuclear facilities and of the waste acceptance processes.

There are safety requirements and license conditions for the transportation and interim storage casks for spent nuclear fuel, subject to authorization by the competent ministry following a mandatory and binding report by CSN. The CSN guide GS-9.03 give the criteria and technical bases for the radioactive waste and spent fuel management plan, that is approved by the ministry and CSN.

In light of the review of the Fukushima Daiichi NPP accident and within the framework of the transposition of the amended Nuclear Safety Directive 2014/87/EURATOM, the CSN in February 2016 issued a Technical Instruction to the licensee ENRESA, requiring a detailed assessment of the events that either directly or indirectly may impact on the structural design of the centralized storage facility or its emergency management. The construction permit review for the CSF included technical instructions, e.g., Design Extension Conditions taking into account severe accident conditions beyond design basis caused by multiple failure situations, such as total loss of power. In addition, a new approach is going to take security into account in design.

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

During the authorisation process review and assessment of safety is conducted by the CSN staff. According to the agreements between CSN and some of the Autonomous Communities, the review and assessment of licensing application is conducted by the Autonomous Communities staff trained by the CSN using the procedures of the CSN. Internal procedures for conducting such review and assessment of application exist, e.g. PT.IV.35 for authorisation of trading of radiation sources and PT.IV.107 for authorisation of a use of accelerators in radiotherapy. Two different types of authorisation exist; registration and licensing.

Members of the IRRS team were informed that in this case Autonomous Communities staff does not perform review and assessment but only check if the documentation is complete. Review and assessment of the facility and activity is performed by authorised UTPRs, which prepare a report submitted to the Autonomous Communities. The report is used by the Autonomous Communities granting a registration. During the lifetime of activity and facility subject of registration the registrant should submit a report to the CSN following graded approach, i.e. for type I a report should be sent once per year while for type II every 2 years as required in the Art. 18 of Royal Decree 1085/2009 approving the regulation on installation and use of x-ray apparatus for medical diagnosis. The content of the report is given in the mentioned article. Among other documentation a report of the UTPR should be attached. The CSN notes the acceptance of the reports. According to the authorisation conditions of the UTPR any non-compliance which is not corrected in time should be reported to the CSN by the UTPR. Inspections of registered practices are performed by Autonomous Communities inspectors accredited by CSN according to the already mentioned

agreements or CSN staff. The CSN is analysing annual reports of the UTPR and performs the inspection of the UTPR.

During the licensing process, CSN prepares a report, which is obligatory for the MITECO or Autonomous Communities following review and assessment of the facility documentation on the basis of which a license is granted. The application which is reviewed by CSN includes safety assessment. Provisions for independent verification of safety assessment when safety assessment is required are missing in the legislation. This issue is addressed in R12. The next step before a start of a practice is a "notification for start-up" which is issued by the CSN to the licensee after a CSN inspection. The Art. 39 of Royal Decree 1836/1999 approving the Regulations on Nuclear and Radioactive Facilities gives provision for the "notification for a start-up". Only after receiving the "notification for a start-up" a licensee can start exercising its licensed activity. All licensees are required to send defined content on compliance with safety requirements to the CSN annual reports with as required by Art.73 of Royal Decree 1836/1999 (Regulation on Nuclear and Radioactive Facilities) and IS-28. The reports are assessed by the CSN inspectors annually.

CSN developed a procedure identifying licensees with potential non-compliances with safety requirements in due time. A list of such licensees is based on all information available. It is updated every four months and used for increased vigilance of CSN, e.g. for inspection planning.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING OF FACILITIES

The CSN has developed management procedures that provide detailed guidelines on the processes for review and assessment of different facilities and activities

Assessment of the application files for a dismantling permit by CSN covers issues related to:

- waste management (radioactive waste and SF management plan),
- the public radioactive effluent control program (PROCER);
- environmental protection during decommissioning (environmental radiation protection program and plan for control of cleared materials),
- public and environmental protection beyond decommissioning (site restoration plan).

For any nuclear or radioactive fuel cycle facility under decommissioning, the license defines the documents to be updated and mentions the frequencies for it.

Application for licenses for design, construction and operation include the technical and economic studies related to future decommissioning of the facility. The license application files contain elements of a decommissioning plan such as the description of the plant, the site restoration plan, the cleared materials control plan and an economic study of the dismantling process. During discussions, the IRRS team was informed that a decommissioning plan, as described in the IAEA standards, has not been defined as such in the current regulations. However, two draft regulations refer to the initial and final decommissioning plan and will complete the current regulations:

- Section 4 of the draft Instruction on basic safety requirements during design, construction and operation of nuclear installations in order to facilitate its future decommissioning develops the review and updating criteria for the documents that constitute the initial decommissioning plan in a more systematic way.
- Similarly, Point 4.2.2. of the draft Instruction on the safe decommissioning, and where appropriate, safe closure of nuclear and radioactive fuel cycle facilities, establishes the review and updating criteria of the final decommissioning plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although elements from a decommissioning plan are included in the license application for construction and operation of a facility, the term "decommissioning plan" is not mentioned in the current regulation. Two draft instructions refer to the initial and final decommissioning plan, however, the required contents are incomplete.*	
(1)	**BASIS: GSR Part 6 Requirement 10, para. 7.4 states that** *"The licensee shall prepare and submit to the regulatory body an initial decommissioning plan together with the application for authorization to operate the facility. This initial decommissioning plan shall be required in order to identify decommissioning options, to demonstrate the feasibility of decommissioning, to ensure that sufficient financial resources will be available for decommissioning, and to identify categories and estimate quantities of waste that will be generated during decommissioning."*
(2)	**BASIS: GSR Part 6 Requirement 11, para. 7.10 states that** *"The final decommissioning plan and supporting documents shall cover the following: the selected decommissioning strategy; the schedule, type and sequence of decommissioning actions; the waste management strategy applied, including clearance, the proposed end state and how the licensee will demonstrate that the end state has been achieved; the storage and disposal of the waste from decommissioning; the timeframe for decommissioning; and financing for the completion of decommissioning."*
S11	**Suggestion: CSN should consider updating the regulatory provisions to require licensees to submit an initial and final decommissioning plan for review and approval and describe the contents of such plans.**

For the deferred dismantling, such as in case of Vandellós I NPP, a periodic safety review of the facility is imposed. For facilities under decommissioning the frequency of periodic safety assessment can be adapted.

The CSN draft instruction on the safe decommissioning, and where appropriate, safe closure of nuclear and radioactive fuel cycle facilities deals with the criteria for elaborating the Study of the Basic Strategies and requirements for multistage dismantling activities. This study includes the alternatives for spent fuel management and the dismantling of the facility, as well as information on novel decommissioning methods to be used during the dismantling operations. This study is presented to CSN for review and to MITECO for approval.

The IRRS team was informed that any modification of the facility or of processes during decommissioning with a potential impact on nuclear safety and radiological protection, as well as experience feedback from operations on site or at other plants (even outside Spain), may trigger a review and assessment process of existing regulatory documents (instructions, license, etc.).

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

In order to prepare the technical safety report as basis for an approval, CSN reviews and assesses applications to provide an independent verification of regulatory compliance by the applicant. CSN published the Safety Guide 6.04: "Documentation to request authorizations for the transport of radioactive material - package approvals and authorization for shipments" to facilitate the preparation of the required

application documents. This Safety Guide is currently being updated in compliance with the IAEA Transport Regulations SSR-6.

The area of Transport of Radioactive Material (ATMR) in CSN carries out and manages the safety review and assessment. If needed, ATMR receives support from diverse specialist areas of the CSN (matrix structure) to carry out technical assessments regarding mechanical and thermal behaviour, radiation shielding, and criticality safety depending on the package characteristics. The criteria for regulatory review and assessment are consistent with and derived from the requirements stipulated in the international transport regulations, and hence, in compliance with the IAEA Transport Regulations SSR-6. The review and assessment processes follow internal procedures (PT.IV.28 "Evaluation for the approval and validation of transport packages" and PT.IV.41" Evaluation of applications to authorize the transport of radioactive material"). These procedures are very detailed and comprehensive and provide a sound basis for a qualified review and assessment of application documents consistent with SSR-6 requirements.

According to para 308 of SSR-6 it is required that the competent authority shall arrange periodic assessments of the radiation doses to person due to the transport of radioactive material. This includes transport workers and members of the public as well. While a dose assessment for transport workers has been performed by CSN a dose assessment for members of the public has not been available so far.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *While CSN performs dose assessments for transport workers as required, dose assessments for members of the public have not been performed.*	
(1)	**BASIS: SSR-6, para. 308 states that** *"The relevant competent authority shall arrange for periodic assessments of the radiation dose to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the Basic Safety Standards*
(2)	**BASIS: GSR Part 4, Requirement 1 states that "***A graded approach shall be used in determining the scope and level of detail of the safety assessment carried out in a particular State for any particular facility or activity, consistent with the magnitude of the possible radiation risks arising from the facility or activity."*
R9	**Recommendation: In accordance with a graded approach, CSN should arrange for assessments of the radiation dose to members of the public associated with the transport of radioactive material to ensure that the system of protection and safety complies with the Basic Safety Standards.**

The CSN has a Transport Database in which all dossiers and data related to the consignors, carriers, package design approvals, transport authorizations, inspections and transport events are registered. Through this database there is direct access to the documents of those dossiers, including the application and the supporting documents, the official communications between the applicant and the CSN, the assessment carried out by the specialist areas, the integrated final assessment with the binding technical report proposal and the final certificate of approval for packages or transports as well as inspection reports and identified events and non-compliances. All this information is linked to each other so that very quickly and

comprehensively assessments and reviews can be carried out to facilitate compliance with regulatory requirements, to obtain feedback from practical experience and to identify any inconsistencies which may lead to future actions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The CSN has a comprehensive transport database in which all dossiers and data related to the consignors, carriers, package design approvals, transport authorizations, inspections and transport events are registered. All this information is linked to each other so that assessments and reviews can be carried out very quickly and comprehensively to facilitate compliance with regulatory requirements, to obtain feedback from practical experience, to perform analyses and to identify any inconsistencies which may lead to future actions.*	
(1)	**BASIS: SSR-6, para. 307 states that** *"The competent authority shall assure compliance with these Regulations."*
(2)	**BASIS: SSR-6, para. 208 states that** *"Compliance assurance shall mean a systematic programme of measures applied by a competent authority that is aimed at ensuring that the provisions of these Regulations are met in practice."*
GP1	**Good Practice: The CSN Transport Database goes beyond the normal scope of databases used in transport by linking together information applicable to different areas of the compliance assurance programme like inspection results, approval certificates, fabricated and used packaging, non-compliances, events during transport which are available for all consignors and carriers in Spain. It provides an excellent tool for the competent authority to improve and facilitate the implementation of its compliance assurance programme.**

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

Review and assessment for occupational exposure belong to the functions of the CSN (Law 15/1980 on the 22th of April, Art.2). Moreover, Article 15 of Royal Decree 783/2001 lays down the principles upon which the operational protection of exposed workers will be based. Art. 20 (Nuclear Facilities) and art.38 (Radioactive Facilities) in Royal Decree 1836/1999 require submittal of documents such as the Radiation Protection Manual and the safety assessment as part of the request for authorization. Review and assessment of exposure optimization, review of monitoring programme, review of occupational exposure reports, and verification of compliance of an authorized practice with the requirements on the dose records keeping for occupational exposure are part of the inspection programme (see 7.8).

The review and assessment during operation is performed through the inspections as described in Royal Decree 783/2001 on regulation on Sanitary Protection against ionising Radiations, which stipulates the procedure and requirements for radiation protection, Art.65, 66, and 67, Royal Decree 1836/1999 on Regulation on Nuclear and Radioactive facilities, which indicate the procedure and the requirements for nuclear and radioactive facilities, Art.43 to 46 (see 7.9). Assessment of individual occupational dose is required in the RD 783/2001, Art.14 ("Estimation of effective and equivalent doses"), in Art.26

(Monitoring of the work environment) in Section 2, Art.27 to 33 (Individual monitoring) in RD 783/2001. In particular, dose monitoring for Cat A and Cat B workers is dealt with in Art. 28 and 29.

For special dose estimation, Art.30 states that "In those cases where it is impossible, or inappropriate, to carry out individual measurements, the individual monitoring shall be based on an estimation performed on the basis of individual measurements made on other exposed workers, or on the basis of the results of the monitoring of the working environment, as laid out in Article 26, with a specific mention to this fact in the worker's dosimetric record".

"The system for the use of dosimeters or instruments employed for area dosimetry and the associated procedure for the allocation of doses must be included in a written protocol, subject to the evaluation and inspection of the Nuclear Safety Council" (RD 783/2001 Art.31).

"In case of accidental exposures, the associated doses shall be evaluated as well as their distribution throughout the body. In cases of emergency exposures, an individual monitoring shall be performed or evaluations of the individual doses, depending on the circumstances" (Art.32).

"Specific study needs to be performed when dose limits are surpassed in case of specially authorized exposure, accidental or emergency exposure" (Art.33).

When, as in case of a specially authorised exposure, an accidental or emergency exposure, the dose limits, established in Article 9, may have been surpassed, a specific study must be carried out to evaluate, with the greatest possible speed and precision, the dose received by the entire organism or in the affected regions or organs (Art. 33). These cases and the results of the studies shall be immediately brought to the attention of the Prevention Service that carries out the monitoring and control functions regarding the workers' health, as well as the Nuclear Safety Council, and the affected worker.

Recording of dose data is mandatory as addressed in RD 783/2001 Art.34. Medical records for Cat A workers need to be established and the dose record of all exposed workers belonging to Category A, must also be incorporated into their respective medical records, referred to in Article 44. For Cat. B workers, the annual doses, determined or estimated, shall be included.

Workplace monitoring is addressed in RD 783/2001 Art.26 which covers the measurements of external dose rates, of concentration in the air and ground contamination, the documents for the registration, the evaluation of the aforementioned monitoring and the use of the results in order to assess the individual doses when appropriate (art.30). The review of the monitoring programme belongs to the tasks of the CSN as indicated in the Law 15/1980 CSN Art. 2(g).

Assessment of external dose is implemented for all activities and facilities. Concerning the assessment of the internal dose, the nuclear facilities and facilities belonging to the fuel cycle have the capacity to assess the dose by means of a whole-body counter. In case of contamination, additional biological assay methods are available and are performed at the CIEMAT and TECNATOM which both are recognized by the CSN. For other facilities, there is at the present time no such capacity, except for incidental or accidental cases where CIEMAT is able to provide for biological assessment of the incorporated activity.

In order to improve the assessment of internal dose for radioactive facilities, such as Nuclear Medicine Services in hospital, a project has been launched in 2015 with the aim of developing an approach based on the identification of tasks for which there should be a need for monitoring the workers and, if needed, to use a technical approach based on gamma scanning as a preliminary assessment of the internal dose. The project will also define the level above which CIEMAT will have to proceed with the assessment of the incorporated activity.

Chapter 4 of RD 783/2001 is devoted to the legal provisions concerning the health surveillance of exposed workers. Section-1 deals with the sanitary monitoring (Art.39), medical examinations (Art.40), prior health

examination (Art.41), periodic health examinations (Art.42), medical classification (Art.43) and medical records (Art.44). Section 2 stress on the case of the "special monitoring" for exposed workers.

6.9. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

There are provisions in the Law and regulations related to review and assessment during authorization process as well as during the lifetime of the facility or duration of the activity regarding medical exposure. Review and assessment regarding occupation and public exposure involving the use of the radiation sources for medical exposure is a subject of a regulatory regime described in 6.5 above are in place.

Although review and assessments regarding to medical exposure i.e., for diagnosis and treatment of patients and exposures of humans in biomedical research are provisioned in the regulations, the IRRS team was not able to verify the implementation of the requirements given in the legislation. This is covered in R1 in Module 1.

6.10. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

Processes for controlling public exposure (surveillance, control, monitoring, and evaluation of doses) are established and implemented. Discharge limits are mentioned in licenses. For activities subject to licensing, the application files, containing documents related to impact evaluation on public and environment, are reviewed by CSN.

According to CSN's Safety Instruction IS-33, on the radiological criteria for the protection against exposure to natural radiation, all industries included on a positive list (list of work activities) have to register with the regional industry authority and to conduct a study on their radiological impact to workers and public. If the corresponding reference levels are exceeded, or when industries produce waste with an activity concentration above the exemption values in Order IET/1946/2013, they remain subject to regulatory control.

Several existing exposure situations that might potentially be of radiological concern have been identified in the country. Out of them, some are related to land or watercourses contaminated by NORM and some to artificial-origin radionuclides. A methodology document for assessing the radiological impact of NORM-industries is available (CSN safety guide GS-11.03).

As an example, the IRRS team was informed about the Palomares accident from 1966, resulting in an alpha contamination of a large area. Immediately after the initial decontamination operation, a radiological surveillance programme was established by Junta de Energía Nuclear (currently, Ciemat). The on-going programme includes the monitoring of air, soil, water, vegetation and foodstuff, as well as voluntary medical exams and urine analysis for the local population.

Changes in land use, by 2000, together with the detailed characterization performed between 2005 and 2007 triggered new control measures, such as restrictions of access to certain areas. The target for clean-up was set at a reference level of 1 mSv/y.

Article 33 of the RD 1836/1999 establishes the requirements that are needed to obtain the decommissioning declaration (license termination). Compliance with the radiological criteria for the release of nuclear facility sites (set in Instruction CSN IS-13 and developed for each specific site in the Site Restoration Plan) is verified by CSN. MITECO, following the CSN report, has the power to establish, if necessary, restrictions to the use of the site land

According to Art. 62 of Royal Decree 783/2001, the competent authority charges the title holders of work activities – not regulated in Article 2.1 – in which natural sources of radiation are present, to conduct the necessary studies in order to ascertain whether there is a significant increase in the exposure of workers or members of the public that cannot be considered negligible from the point of view of radiation protection.

CSN is charged with the inspection of such activities.

Radiological protection of public and environment and compliance with authorized limits is verified/ensured through the implementation of a series of CSN approved effluent control, monitoring and evaluation programs such as the radiological environmental monitoring program and the radiological effluent control programme, both developed in the off-site dose calculation manual (MCDE). Parameters such as dilution factor at the receiving water body, atmospheric dispersion coefficients or water and land use are periodically reviewed by the licensee according to the frequency established by CSN in the MCDE. At least once a year CSN performs an independent verification of the dose impact associated with the discharges.

Besides monitoring of discharges of gaseous and liquid substances by the licensee, Spain has a radiological environmental monitoring infrastructure. This system is implemented by 19 university laboratories of different Autonomous Communities, and 2 research centres (CIEMAT and CEDEX). The CSN has also promoted a global process of harmonization and achievement of a high-quality performance of the laboratories. Each year an inter comparison exercise is organized by CSN as well as a workshop to present its outcome.

Over the years, the CSN has promoted and sponsored several radon measurement campaigns, collecting over 14000 radon measurements in dwellings. About 10 % of it exceeds the reference level of 300 Bq/m³ at ground level in the radon prone areas. Public information on radon levels in Spain has been released by the CSN on a regular basis. A methodology document for assessing Radon exposure or doses is available (CSN safety guide GS-11.04). With respect to the development of a national action plan to control public Radon exposure, a number of actions have been realized (see also 6.11):

- Strategy for conducting surveys of indoor radon concentrations;
- Development of a national radon risk map and definition of radon prone areas;
- Regulatory control of radon exposures at the workplace, including mandatory radon measurements at underground workplaces and those where groundwater is processed or utilized;
- Requirements for radon measurement laboratories and accreditation under ISO-17025;
- Strategy to mitigate radon entry in new buildings;
- Communication to the public on radon risk.

This action plan is pending approval by Ministry of Health.

This issue was acknowledged, and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although Spain has completed a number of actions as part of its efforts to assess indoor Radon exposure to members of the public, such as the development of a national Radon risk map with definitions of radon prone areas, the action plan itself has not been completed or approved.*	
(1)	**BASIS: GSR Part 3 Requirement 50, para. 5.20 states that** *"Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered as required in para. 5.19(a), the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings, which includes …"*

(2)	**BASIS: GSR Part 3 Requirement 50, para. 5.21 states that** *"The government shall assign responsibility for:* *a) Establishing and implementing the action plan for controlling public exposure due to Rn-222 indoors;* *Determining the circumstances under which actions are to be mandatory or are to be voluntary, with account taken of legal requirements and of the prevailing social and economic circumstances."*
R10	**Recommendation: The government should ensure that a national radon action plan be completed and approved, comprising coordinated actions to reduce activity concentrations of radon in existing and future buildings, and assign responsibilities for establishing and implementing this action plan.**

6.11. SUMMARY

The review of this area indicated that all the aspects are covered by CSN during the review and assessment of licensing submissions from nuclear installations and radioactive facilities. However, the IRRS team identified the following areas for improvement:

- Updating the existing regulatory provisions to require licensees to submit an initial and final decommissioning plan for review and approval and description of the contents of such plans.
- Arrangement for assessments of the radiation dose to members of the public associated with the transport of radioactive material to ensure compliance with the Basic Safety Standards
- Ensuring that a national radon action plan be completed and approved, in order to reduce activity concentrations of radon in existing and future buildings implementing this action plan.

In addition, it was distinguished by the IRRS team that the CSN Transport Database goes beyond the normal scope of databases used in transport and thus provides an excellent tool for the competent authority to improve and facilitate the implementation of its compliance assurance programme. This was regarded as a Good Practice in the framework of review and assessment.

The description provided in the advanced reference material regarding this module was systematic and comprehensive and provided ample support in the peer review by the IRRS team.

7. INSPECTION

7.1. GENERIC ISSUES

CSN has established a comprehensive program of inspections that is compatible with IAEA safety standards. Specifically, CSN has produced the "Framework for the Inspection Function of the Nuclear Safety Council" (Framework), last revision dated 29 November 2017, which includes criteria for carrying out independent inspections at all nuclear and radioactive facilities and activities, including those that are licensed by Autonomous Communities. The Framework provides for:

- A detailed set of management (PG series), technical (PT series) and administrative procedures (PA series)
- A graded approach to inspection scope and frequency
- Inspections during various phases of operation (e.g., construction, operation, decommissioning)
- A range of inspection types (e.g., control, licensing, reactive and special), including planned and not planned inspections
- A range of inspection techniques (e.g., in-process observations, document reviews, interviews)
- Interactions with registrant and licensee staff and management
- Inspection reporting that is made available to external stakeholders
- A means to ensure that identified deficiencies are corrected in a timely manner
- Periodic evaluations of CSN's compliance with its specific facility and activity inspection programs

The Framework also provides for the assignment of certain inspection activities to the Autonomous Communities, as well as direct CSN oversight of certain of these activities.

Finally, all CSN inspectors receive adequate training to conduct their work and are afforded unimpeded access to registered and licensed facilities and activities, including unannounced inspections.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

The "Framework for the Inspection Function of the Nuclear Safety Council", established the general framework for the CSN's inspection process that, for NPP, is developed into the CSN management procedure PG.IV.03 "Inspection and control on nuclear and fuel cycle installations". It includes instructions and criteria for carrying out independent inspections at nuclear power facilities. This framework provides for a graded approach to inspections that is based both on deterministic criteria and site-specific risk insights gained from detailed probabilistic safety assessments (PSAs). Inspections at power reactors are one element of the overall oversight regime of Spanish nuclear power plants (known as the "Integrated Nuclear Power Plant Supervision System" or SISC) that is explicitly defined in CSN management procedure PG.IV.07. Inspections performed under the SISC include a minimum set of "baseline" inspections that are conducted at each power reactor site every inspection cycle regardless of a site's safety performance. A fundamental element of all CSN inspections is a review of a licensee's ability to self-identify and correct their own performance problems.

Consistent with internal procedures, CSN develops an Annual Work Plan for each nuclear power plant site that describes all the planned inspections (both "systematic" and "non-systematic inspections) for the year at each site, except for unannounced inspections. These latter inspections are conducted at least three times per year (approximately once per quarter) by resident inspectors. Reactive inspections are also performed in response to incidents that occur at nuclear power plants based on risk-based and deterministic criteria. The scope and timing of reactive inspections vary depending on the specifics of the incident involved. "Special inspections" are also performed at the discretion of CSN, and when following up on "complaints" received. Such complaints can be received by a variety of external stakeholders. Special inspections can

also include a review of nuclear component suppliers (vendors), but only in conjunction with a licensee's own inspections of these entities. CSN has not established a systematic vendor inspection program; rather, CSN inspectors assess the adequacy of licensee quality assurance programs with respect to procurement of safety-related components.

Inspections are performed by both resident inspectors (of which there are at least two assigned to each power reactor site) and headquarters-based specialist inspectors. Consultants are rarely used as CSN has maintained on staff adequate numbers of sufficiently trained inspectors for each technical discipline. As of the date of this mission, CSN employed approximately 225 technical staff, of which more than 100 were competent in conducting inspection activities (45%) at nuclear power plants. CSN regulations require that licensees provide agency inspectors full, unfettered access to their facilities, meetings, procedures, documents and staff at any time or upon request. Instruction IS-14, dated 24 October 2007, establishes specific requirements regarding the roles and responsibilities of resident inspectors.

During a site visit to the Vandellós 2 nuclear power plant, the IRRS team observed the activities of a headquarters-based inspection team (three CSN staff) performing a focused evaluation of the unit's ultimate heat sink and associated structures, systems and components. This multi-disciplined team was observed to engage the plant staff in challenging dialogue, perform thorough field "walk-downs," and review documented licensing basis information. Interviews with the two resident inspectors assigned to the facility confirmed that these individuals maintained day-to-day oversight of safety-related activities at the plant.

Comprehensive inspection reports are published and included on the CSN's website, typically within two months of the conclusion of each inspection. Resident inspector reports are published quarterly. Each potential inspection finding that is "more than minor" and potentially "greater than green" significance is assessed by a team of experts and managers at CSN headquarters using a well-defined significance determination process (SDP). Where possible, the SDPs utilize PSA tools to quantify the safety (risk) significance of inspection findings. All findings are assigned a colour (i.e., green, white, yellow or red) depending on their safety (risk) significance. Each finding is then documented in a separate "findings report"; the main conclusions of this report are provided to the licensee, (but the findings report is not made publicly-available). The findings report provides the final CSN decision on the significance (i.e., colour) of the finding and the associated basis for the decision. Draft reports of inspections and findings are provided to the licensee for review and comment prior to finalization. CSN considers any input received by licensees on these reports. Licensee-provided comments on draft CSN inspection and greater than green findings are included in a final report, along with a summary of which comments were accepted or rejected (along with a basis). A brief summary of each inspection finding, and its significance is posted on the CSN website for public review.

Of particular note, CSN has placed a strong emphasis on promoting a robust safety culture at its licensed nuclear power plants. In addition to having established a legally-binding requirement on licensees to ensure they conduct periodic safety culture self-assessments (CSN instruction number IS-19), CSN actively inspects the quality of these licensee self-assessments and evaluates licensee actions completed and planned to address issues identified during the assessments. Safety culture assessments can also be mandated in a reactive manner when significant incidents arise at nuclear power plants or when a pre-established number of "cross-cutting components" are indicated over a four-quarter period from documented inspection findings. CSN has established a robust methodology to assign, track and report on cross-cutting components, and, if specific thresholds are exceeded, has defined actions to require the affected licensee to take corrective actions.

At the end of each calendar quarter, inspectors and managers meet at CSN headquarters to conduct a comprehensive review of all the inspection findings, cross-cutting components, and performance indicators to assess the integrated safety performance of each nuclear power plant. A report is produced from this

meeting that is shared with each licensee (but not made publicly-available except a summary, by means of a press note). Inspection findings are tracked in an electronic database and remain open (active) until a follow-up inspection confirms that these matter(s) have been adequately resolved. Established inspection plans are adjusted based on this quarterly assessment to accommodate CSN-assessed changes in licensee performance, consistent with the SISC "action matrix."

At a nominal biennial frequency, and consistent with procedure PA.IV.207, "SISC Self-Evaluation Program," CSN performs a comprehensive self-assessment of SISC implementation and documents the results along with recommendations for program improvements. The most recent SISC self-assessment, for example, included a recommendation to "streamline" inspection report documentation. Operating experience is also fully considered and used to modify the inspection program as appropriate.

CSN recognizes the importance of having well-trained staff who possess good technical and communication skills prior to assigning them to conduct inspections at nuclear facilities. Inspector training is provided as needed based on the experience of individual staff members and the facilities and activities to which they will be assigned to inspect. Formal records of completed training activities are included in each individual inspector's file maintained by CSN human resource staff. However, CSN has not established a systematic approach to inspector training and qualification (i.e., certification). As such, there is no formal means to ensure that inspectors are consistently trained to a minimum standard of requisite knowledge, skills and abilities to complete their assigned inspection activities. As part of the IRRS team site visit to Vandellós 2, plant management expressed some views that the CSN resident inspectors were not fully knowledgeable of the plant's specific design and operation upon their initial assignment to the facility. Over time, the resident inspectors gained sufficient knowledge in part through their questioning and interactions with plant staff. Suggestion S5 in Section 3.3 of this report specifically addresses this matter.

7.3. INSPECTION OF FUEL CYCLE FACILITIES

The CSN Framework document described in Section 7.1 above, along with procedure PG.IV.13 "Supervision and control of Juzbado fuel fabrication facility" establishes a specific baseline inspection program for the Juzbado fuel fabrication facility. These inspections cover 19 specific areas, including safety of operations, radiological controls and installation support. The PG.IV.13 procedure also describes supplementary inspections conducted by CSN when incidents in the operation of plants occur.

The baseline inspection program described above is to be amended this year to include weekly "reinforced inspections" that builds on the experiences gained from resident inspection practices at operating nuclear power plants (i.e., procedure PT-IV-88). These weekly one-day inspections focus on plant status, required surveillance tests, and operational events. Compliance with Complementary Technical Instructions is also confirmed. CSN piloted this new inspection approach at Juzbado for about one year and a self-assessment of the pilot program is ongoing.

The IRRS Team observed a reinforced inspection at Juzbado that covered a review of the previous week's daily reports, follow-up on relevant issues in the factory, a review of non-conformities captured in the Corrective Actions Database, a visit to the control room and an inspection of a diesel generator surveillance test. The inspectors demonstrated good technical and communications skills in performing the inspection, consistent with CSN procedures.

During a discussion with plant management, ENUSA expressed content with the competence of CSN inspectors and their commitment to safety. Some concern was expressed that the new (and more frequent) reinforcement inspections are not formally described in the CSN instructions and that the regulations for nuclear installations are modelled for operating nuclear power plants. As such, these regulations do not fully account for the different design and operation particular to fuel fabrication facilities.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

The CSN inspection program for radioactive waste management facilities is described in procedure PG.IV.03. The procedure PA.IV.01 on Basic Inspection Plan establishes the annual work plan, including scheduled licensing and control inspections, that cover the different fields of inspection and the areas to be inspected with various frequencies. Inspections of the El Cabril radioactive waste disposal facility cover 18 discrete areas. The scheduled inspections are grouped into the fields of operation, emergency preparedness, radiological controls and maintenance area, surveillance and technical support. The procedure PG.IV.15 "Supervision and monitoring system of the El Cabril disposal centre" describes the supplementary inspections carried out to provide the CSN with more information when following up on incidents. Basic Inspection Plan for nuclear power plant includes specific inspection procedures for waste management activities.

The main technical inspection procedures implemented are:

- PT.IV.96 Inspection of temporary radioactive waste storage at nuclear facilities
- PT.IV.253 Inspection of low and intermediate waste (LILW) management activities
- PT.IV.102 Inspection on the management activities of radioactive waste at nuclear facilities others than nuclear power plants in operation
- PT.IV.15 Inspection to control the process of acceptance of low and intermediate level waste for storage at El Cabril

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The CSN has altogether six inspectors to perform radiation source facility and activity inspections, all of whom possess at least a Master of Science degree in natural science and/or in radiation protection. Further, each of these CSN staff have passed an agency examination and completed on-the-job training. On a voluntary basis, some Autonomous Communities also have facility and activity inspectors who are accredited by CSN. In all, there are 17 non-CSN inspectors who are conducting inspections on behalf of the CSN. However, there is no formalised procedure regarding training of the CSN headquarters inspectors. Suggestion S5 in Section 3.3 of this report specifically addresses this matter. All inspections are conducted using CSN procedures.

All radioactive source facility and activity inspections are scheduled and conducted in accordance with the CSN Annual Work Plan. This plan is based on graded approach. For example, all Category 1 facilities and practices involving Category 1-3 sealed sources are inspected at least once per year, while Category 2 facilities are inspected on a biannual basis. The Annual Work Plan includes both announced and unannounced inspections. Reactive inspections are routinely conducted following incidents, as appropriate. Inspections are performed consistent with CSN procedure PT.IV.31, which include independent measurements. Approximately 1400 inspections were conducted in 2017.

The IRRS Team observed an inspection of large industrial radiography facility in Madrid (i.e., SGS Tecnos, S.A.), which was performed by a team of CSN-accredited inspectors; no issues or concerns were identified.

Finally, the Team noted that CSN was organizing a 3-day meeting of all CSN-accredited inspectors to harmonise inspector practices all over Spain and to improve the efficiency and effectiveness of associated inspection activities.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

Inspections of facilities under decommissioning are performed in accordance with CSN procedures PA.IV.10 (preparation and performance of inspections to Nuclear, Fuel Cycle and Waste facilities), PA.IV.08 (preparation, processing and management of the Nuclear Facility Report), PA.IV.09 (Processing

of deviations derived from CSN inspections to Nuclear and Fuel Cycle Facilities) and PA.IV.03 (Inspection and Control of Nuclear and Radioactive Fuel Cycle Facilities).

For nuclear power plants undergoing decommissioning, CSN maintains at least one resident inspector on site who actively monitors ongoing decontamination and dismantlement activities, as well as assure compliance with relevant safety requirements.

Licensee inform CSN of all discharges to the environment. Reports on quantities and activities of materials leaving the decommissioning site are also provided to CSN. As specified in the technical specifications, licensees must inform CSN immediately when predefined activity levels for discharging effluents are exceeded. In addition, the Automatic Stations Network enables CSN to monitor radioactivity levels in the atmosphere in real time.

The IRRS team observed an inspection performed at the José Cabrera nuclear power plant, at which ENRESA began active decommissioning and dismantling in 2010. At present site activities are focused on the decontamination of building structures and on-site restoration (i.e., removal of contaminated grounds). Spent fuel is temporarily stored on site in dry storage.

The Team noted that the CSN inspection was conducted in a very professional, transparent and constructive manner. The Team did not identify any issues or concerns with the CSN inspection. Inspectors conducted the entrance meeting in the presence of the responsible ENRESA management, the chief inspector of CSN, and the site resident inspector. The inspection agenda had been communicated to ENRESA in advance of the meeting and comprised four main areas:

- Observation of the main decommissioning activities ongoing at the facility
- Review of compliance with the limits and conditions of the design modification approved by CSN in 2018. This comprised the adaptation of the former cooling tower zone as a storage area for VLLW, and the soil washing installation
- Verification of compliance with surveillance requirements
- Plant tours to assess in-progress decommissioning activities, evaluate the storage area for material waiting for clearance control, inspect the storage area for very low-level waste VLLW, and confirm continued regulatory compliance of the interim spent fuel storage installation

Discussions revealed that clearance of materials at the plant was applied correctly. The clearance process followed the methodology described in the cleared material control plan (part of license application) which was comprised three steps: (1) a measurement to identify candidate materials for release, (2) a 100 % measurement of the materials in an area with low background (thereby rejecting 20-30 % that becomes VLLW) and (3) a quality assurance measurement of about 5% of the clearable materials. The inspection revealed no specific findings. The meeting was then officially closed. CSN planned make the report and send it to ENRESA for acceptance.

The IRRS team observed ENRESA's soil washing installation located on the decommissioning site. The purpose of the process is to minimize the amount of soil classified as radioactive waste.

Following the inspection, the IRRS team held a separate discussion with the resident inspector. This inspector confirmed that interactions with ENRESA were open, efficient and constructive. Inspection reporting (type and frequency) was also discussed by means of example reports. The resident maintained frequent contact with CSN headquarters and with resident inspectors from other nuclear facilities (at least twice a year). Separate conversations with the Site Director confirmed that contacts with the resident inspector were very constructive and professional.

7.7. INSPECTION OF TRANSPORT

The CSN's radioactive transport inspection program is in full compliance with the requirements of SSR-6 and supporting Safety Guides. About 60 inspections focused exclusively on radioactive material transport activities are performed each year, and are comprised of the following types to verify that the responsible party complies with all the safety requirements:

- Shipment inspections upon departure and receipt, and for in-transit storage
- Inspections on the management of the activity by consignors and carriers (management inspections)
- Inspections related to the application of the Radiation Protection Programme or Quality Assurance Programme
- Package test inspections
- Packaging manufacturing inspections
- Inspections related to events

Transport-related inspections are performed by both CSN and Autonomous Community inspectors (according to the Entrustment Agreement between the CSN and Autonomous Communities).

The CSN inspects the transport of radioactive material by all modes (i.e., land, air, and sea), focusing on nuclear safety and radiation protection, and maintains specific Memoranda of Understanding (MOUs) with pertinent authorities to facilitate these inspections. These MOUs also clarify the interfaces with these other competent authorities.

The CSN transport inspection activities are comprehensive and well-structured based on a graded approach. Inspections are planned, conducted in accordance with established procedures, and utilize detailed checklists. These checklists take international experience into consideration and include recommendations of the European Technical Guide "Compliance Inspections by the European Association of Competent Authorities on the Transport of Radioactive Material," Issue 1, February 2015.

Both announced and unannounced inspections are performed. Reactive or special inspections are also performed, usually because of increased regulatory control following incidents, complaints, or the assessment of package manufacturing reports, shipment reports, etc.). The results of every inspection are documented in an inspection report, which are uploaded to the CSN website. CSN carries out periodic analyses of the results of the inspections.

The CSN published Instruction IS-39 on the control of manufacturing of packaging for radioactive material, which is complementary to the Royal Decree 97/2014 regarding the control of manufacturing of packaging for dangerous goods. Regarding transport of spent nuclear fuel, CSN has developed a specific procedure PT.IV.84, "Inspection of the fabrication of spent fuel casks." It is expected that more packages for the transport and storage of spent fuel will be manufactured in Spain in the future. Because of the high safety significance and long-term use of the components of these packagings, CSN should consider strengthening its future inspection program to expand the frequency and scope of spent fuel storage and transport package inspections to ensure that each packaging manufactured complies fully with the design specifications approved by the competent authority.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *CSN's program of inspections for manufactured packagings is focused primarily on production processes. However, it does not consider sufficiently final compliance inspections for each packaging manufactured and used for transport and/or storage of spent fuel.*	
(1)	**BASIS: TS-G-1.5, para. 4.87 states that** *"Manufacturing facilities and subcontractors may be subject to inspections by the competent authority. The frequency and extent of such inspections should be determined by the level of confidence that the competent authority has in the manufacturing arrangements and by the importance to safety of the package features concerned."*
S12	**Suggestion: CSN should consider enhancing the inspection program to include verification of the adequacy of the documentary evidence that each packaging used for spent fuel storage and/or transport is manufactured in compliance with the approved design specifications.**

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

Royal Decree 783/2001 Art. 65 states that *"All those practices, activities and entities mentioned in article 2 of this present Regulation shall be subject to an inspection regime, which will be implemented by the Nuclear Safety Council, from the perspective of protection against ionizing radiation."* CSN is designated as the competent inspection authority to verify authorized party compliance with mandatory radiation protection programs.

The CSN has developed several procedures and technical instructions with the aim of ensuring compliance with occupational radiation protection requirements including, for example "as low as reasonably achievable" (ALARA) assessments, radiation and contaminated area access controls, dosimetry, instrumentation, and training. The occupational exposure inspection program is based on a graded approach such that the scope and frequency of inspections consider the characteristics of the facilities and the level of risk they present.

7.9. INSPECTION OF MEDICAL EXPOSURE

Royal Decree 1132/1990 Article 4, dated 14 September, assigns the Competent Autonomous Community Health Authorities the responsibility to inspect all sanitary facilities, including radiodiagnosis, radiotherapy and nuclear medicine, and to provide for the radiation protection of patients undergoing medical examinations and treatments, as well as exposures of humans in biomedical research. The IRRS team was not able to verify the adequacy of the scope and/or type of inspections performed at these facilities. This is covered in R1 in Module 1.

The Law 15/1980 dated 22 April, Royal Decree 783/2001 dated 6 July, and Royal Decree 1836/1999 dated 3 December, assign CSN the responsibility to verify that all facilities that use radiation sources for medical purposes provide for protection from occupational and public radiation exposure. The IRRS team confirmed that CSN has a specific program of inspections of these facilities as part of the Framework described in paragraph 7.1 and 7.5.

During a site visit to the Hospital Puerta de Hierro, located in Madrid, the IRRS team observed a CSN inspection of licensee documents and instrumentation. The inspection was started with a round table discussion/interview with the Acting Head of the Radiation Protection Service (RPC), as the radiation protection officer, and relevant staff from the Radiotherapy and Nuclear Medicine Departments. An inspection procedure was followed in accordance with CSN's management system as applied to medical facilities.

7.10. INSPECTION OF PUBLIC EXPOSURE

Licensees monitor and control radioactive effluents through the sampling and analysis programs approved in the facility licensing process and estimate doses to the public by applying the methodology specified in the approved off-site dose calculation manual (MCDE). Additionally, the license holders assess the levels of radioactivity in the environment through the radiological environmental monitoring program (PVRA). For nuclear facilities, this data is provided to CSN on a monthly and annual basis.

Since 2009, the European Commission has undertaken three verification missions under Article 35 of the EURATOM Treaty, the most recent of which was completed in July 2018 regarding discharge and environmental monitoring (and national environmental radioactivity monitoring networks) near the Almaraz NPP.

Detailed information on every discharge of radioactive effluents is submitted monthly and stored in the CSN effluent database (ELGA). All the information on environmental surveillance is stored in the CSN database of radiological environmental data (KEEPER), and the most relevant is available to the public at the CSN website. Nuclear power plants are provided with a continuous measuring network of gamma dose rate stations and with a radiological environmental monitoring program in emergency situations (PVRE), to take samples and perform measurements near the plant in case of emergency. As part of the PVRE, nuclear power plants are provided with mobile units that have portable equipment to take samples and conduct measurements. The PVRE is regularly inspected by the CSN, pursuant to the procedure PT.IV.260, "Inspection of the preservation of the emergency response capacity."

The effluent control and environmental monitoring programs are included among the programs to be considered in the Periodic Safety Review of the facility.

Each Autonomous Community maintains a registry of work activities with enhanced exposure to natural radiation (radon in workplaces and NORM industries). In 2018, 92 activities and industries were registered. CSN has developed and implemented an inspection program for NORM industries. For these inspections, procedures of radioactive facilities have been adapted to the specific characteristics and peculiarities of these activities. Inspections of NORM activities and industries began in 2017. The IRRS team understood that this programme, combined with other strategies, has achieved a significant increase in the associated oversight activities.

The CSN is responsible for evaluating remediation plans and inspecting the site after restoration has been completed, regardless of the origin of contamination (RD1836/1999, art. 81). The remediation plan may include a monitoring plan during and after completion of remedial actions.

MITECO, CSN and ENRESA organized collection campaigns for orphan sources in 2007-2008. In the period 2001-2011, 11 incidents with sources happened, resulting in shutdown of facilities ranging between 2 and 45 days, resulting in a total radioactive waste volume of 880 m^3. Detection of radioactive materials (sources) at foundries or at facilities collecting metal scrap and at recycling plants is arranged via the "Spanish protocol."

7.11. SUMMARY

CSN has established a comprehensive program of inspections that is compatible with IAEA safety standards, specifically GSR Part 1. The "Framework for the Inspection Function of the Nuclear Safety Council" ensures that independent inspections are conducted at all nuclear installations and radioactive facilities and activities, including those that are licensed by Autonomous Communities, consistent with a graded approach. CSN's approach to ensuring an effective safety culture is maintained at nuclear power plants is a good performance of the regulatory oversight program.

The CSN can enhance their inspection framework by:

- Updating transport inspection procedures to include documentary evidence that each spent fuel storage and/or transport packaging is manufactured in compliance with approved design specifications, and
- Establishing a more systematic approach to training and qualification of inspectors.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

Law 25/1964 on Nuclear Energy provides the overarching legal framework for any activities involving the exposure to ionising radiations. On this basis CSN has a very established and comprehensive set of Management Procedures and processes which address all of its requirements.

CSN implements a graded approach in the application of its enforcement in response to any non-compliance by authorised parties to the regulatory requirements or any conditions specified in the authorisation. The graded approach is defined in primary legislation which identifies risk-based non-compliances as minor, serious and very serious which are commensurate with the safety significance of the non-compliance (Article 86 of Law 25/1964). Separately, Article 87 of Law 25/1964 contains criteria to assist in the interpretation of the non-compliances for each of the three levels.

The minor, serious and very serious criteria are consistent for all authorized parties covered by the legislation from nuclear power plants, nuclear installations through to other (non-nuclear) radioactive facilities, transport and medical facilities etc. The criteria are based upon the severity of the potential danger or risk of the non-compliance. Minor non-compliances are defined as those associated with no danger to the safety or health of people, where there has been no exposure to radiation or the exposures are within legal statutory (internationally defined) limits. Serious non-compliances are defined as those where there has been an exposure to radiation which exceed the legal statutory limits. Very serious non-compliances include those were exposures to ionising radiation to people and the environment which could pose a danger to safety and health and where the statutory limits have been greatly exceeded.

The CSN's Nuclear Safety Council Instruction IS-10 establishes the criteria for reporting events to the Nuclear Safety Council by nuclear power plants (there are equivalent CSN's instructions for radioactive installations events and for transport events). In addition to these formal reporting arrangements; this is further supplemented by CSN's processes for the reporting events, which is achieved through the implementation of its comprehensive inspection and assessments regime. CSN Management Procedure PG.IV.03 (Revision 3) Inspection and Control of Nuclear Installations and Fuel Cycle Facilities define the actions to be taken by CSN as a result of its inspection and supervision activities in NPP and fuel cycle facilities (there are equivalent CSN´s procedures for radioactive installations and other regulated activities, and transport). Depending upon the safety significance of any finding, the procedure defines the requirement for further inspection, the suspension of nuclear activities, the issue of formal enforcement action through letters and notifications; and ultimately the proposal to the Ministry to impose financial sanctions. The financial sanctions defined in the primary legislation are given in CSN Management Procedure PG.IV.05 'CSN's Sanctions' Procedures for Nuclear Safety and Radiological Protection'.

Overall on the basis of the IRRS Peer Review of CSN's Enforcement Policy, the requirements of GSR Part 1 Requirement 30, are considered to be accomplished since CSN has fully established, mature enforcement procedures which are compatible with the appropriate IAEA Safety Guides.

8.2. ENFORCEMENT IMPLEMENTATIONS

CSN's implementation of its enforcement processes are intended to deliver a system that ensures a commensurate response to any non-compliance with the regulatory requirements or conditions specified in the authorisation.

A key element of the CSN inspection, assessment end enforcement regime is the ability of CSN to request additional safety analysis to be undertaken by the licensee. To this end, CSN is able to use its own technical specialists to assess any of the additional safety analysis. In the case of technically complex safety analysis,

CSN can make use of external consultants to provide any necessary support or advice. Through its enforcement processes (but not only) CSN is legally empowered to require modifications to be made to a nuclear facility. For those modifications with nuclear safety implications that requires authorisation as result of the application of the CSN's instruction IS 21, CSN's technical specialists will complete an assessment of the proposals and make a recommendation through its normal management procedures to CSN's Plenary Board. Subject to the endorsement by the CSN Plenary a recommendation on the implementation of the modification is made to the Ministry since this may involve an amendment to a facility's authorisation.

CSN is empowered through the primary legislation to amend or revoke a licence or authorisation. CSN is able to propose amendments to a licence; however, this would need to be supported by the Ministry, that is obliged to do it regarding to nuclear safety or radiological protection. Similar processes are in place to allow CSN to revoke a licence. CSN has never proposed to the Ministry the revocation of a nuclear power plant licence. In the case of non-nuclear power facilities, i.e. radioactive facilities and other enterprises providing associated activities, any recommendation by CSN for the revocation of an authorisation would need to be considered by the Autonomous Communities or MITECO.

Through the primary legislation and according to the Management Procedure PG.IV.03, CSN has powers to suspend activities and shutdown plant operations in the event of risk, or "manifest danger" to nuclear safety. The procedures to suspend or shutdown operations recognise the nuclear safety significance and nature of the activity, process or operation. Whilst CSN Resident Inspectors would not themselves be empowered to direct a facility to shut down, CSN could take this decision following the assessment of any advice it receives. Any decision to shut down a facility would be subject to an assessment by technical and legal experts within CSN which would then make a proposal to the Technical Directorate for endorsement by CSN Plenary Board for recommendation to MITECO.

CSN is empowered through the primary legislation to stop activities being carried out by authorised parties. CSN Site Inspectors are able to shut-down an activity by giving verbal notification to the authorised parties. However, in the event that the shut-down of an activity was likely to be for an extended period, then the CSN Site Inspector would inform CSN of any recommendation since the consequences of these proposed actions may need to be assessed by CSN technical experts before a recommendation was made to CSN's Technical Directorate and formal endorsement was obtained from the CSN Plenary (Council). Subject to the acceptance of the CSN Plenary a formal written notification would be provided to the authorised body.

CSN is able to propose to the Ministry for the Ecological Transition prosecution of a licensee based upon evidence revealed from its inspections that there has been a non-compliance with the regulatory requirements or any conditions specified in the authorisation. Any proposal to prosecute would be based upon the safety significance of the non-compliance when compared to the specific criteria identified in the primary legislation. If the non-compliance is considered to meet any of the defined infringements given within the catalogue of infringements identified in the primary legislation, then a proposal to prosecute will be made by CSN. Any proposal to prosecute a licensee will have been fully assessed and verified by CSN's technical and legal experts before being endorsed by CSN's Technical Department and subsequently accepted by the CSN Plenary body. This proposal will be made to the Ministry (MITECO) in case of nuclear facilities or the Regional Government bodies in case of radioactive facilities.

Any notifications that are issued by CSN include a comprehensive list of the specific non-compliances that have been revealed as a result either its inspection or assessment processes, or that been formally reported to it. The list of non-compliances is normally attached as an appendix to the formal notification. The notification provides the legal instruction that the specific deficiencies must be corrected within timescales that are stated in the notification.

CSN's procedures require that confirmation is carried out to ensure that any corrective actions have been effectively implemented. The enacting legislation provides for CSN to carry out further enforcement action

in the event that there has been any failure to carry out the actions to solve the non-compliances within the specified timescales. The further enforcement is achieved by the imposition of an immediate sanction. The primary legislation enables CSN to impose a financial cost of 10% of the full penalty prescribed in law for the non-compliance. This penalty becomes payable directly to CSN without any need for any separate legal process through the courts. A further failure to demonstrate the effective implementation of the necessary corrective action results in a second financial cost of 20% of the full penalty prescribed in the legislation. This approach effectively provides an incentive and impetus to the duty-holder to ensure that the effective implementation of the necessary corrective actions have been completed to the satisfaction of CSN.

The IRRS team established that MITECO and the Autonomous Communities follow the procedures as required by the overarching Laws and the relevant Royal Decrees. In the case of enforcements relating to non-compliances that do not present an immediate radiological risk, MITECO and the Autonomous Communities are required to put in place enforcement measures, and penalties. Such penalties are based on CSN proposal's which includes an assessment of the degree of severity of the licensees' non-compliances. The IRRS team was informed that there have been some instances in which the Autonomous Communities have not informed the CSN of certain enforcement measures that have been implemented against authorised bodies. In those cases where there has been no feedback from Autonomous Communities, CSN has been unable to reflect the enforcement actions that have been made in its inspections. The CSN has no formal procedure to receive such notifications from Autonomous Communities. In view of this shortfall, the IRRS team considered that the formal arrangements need to be reinforced.

The legislation and CSN's enforcement processes provide the opportunity for a licensee or authorise to submit an appeal against any enforcement that CSN has taken. CSN was able to provide a recent example of an appeal that was made in relation to enforcement action that was taken against a nuclear power plant; therefore, CSN was able to demonstrate that its legislation and procedures are in full alignment with the requirements of IAEA requirements on this matter.

With respect to enforcement of nuclear facilities, CSN has been able to demonstrate that its management systems and their implementation are fully consistent with IAEA Safety Guide GS-G-1.3 'Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body'.

Regarding to transport, the enforcement actions of CSN follow procedure PG.IV.12 Control of the transport of radioactive material, CSN Instructions IS-34 and IS-32 establish criteria on actions to be taken and reports to be submitted to CSN in the case of non-compliances and events. Taken together, CSN's Transport Enforcement system meets all relevant provisions outlines in IAEA Safety Guide TS-G-1.5 Compliance Assurance for the Safe Transport of Radioactive Material.

The full range of enforcement powers are provided to CSN through the primary legislation. The CSN Inspectors are able to take immediate enforcement action by giving verbal instructions to the duty holders, for example, the cessation of a particular activity. This is defined in written warnings, which may include the formal notification of identified non-compliances together with the corrective actions that need to be put in place, are issued by CSN. Prior to the issue of a formal written notice, which could result in financial penalties being incurred, the non-compliance would have been assessed and verified by CSN's technical and legal specialists.

CSN's management arrangements are intended to provide transparency and openness in relation to its enforcement process and the outcome of its decision making. Every three months a meeting is held at CSN headquarters to undertake a review of the regulatory activities; i.e. inspections and assessment and the associated ratings, that have been carried out at the nuclear power plants. As part of this review any enforcement that has been carried out during the period will also be discussed. A formal record of this quarterly meeting is produced, and this is subsequently shared with each licensee.

Additionally, as required by CSN's management procedures, there is a thorough review of the regulatory activities that have been carried out over the last twelve-month period. This review considers the results of the inspections that have been carried out, inspection ratings, the status of any outstanding corrective actions etc. together with any enforcement action that has been carried out during the period.

Separately, CSN prepare an annual report on any enforcement that it has taken in relation to radioactive facilities and activities with radiation sources. This annual report is produced in accordance with CSN Procedure PT.IV.109 and provides details on the number of warning notices and any fines that may have been imposed.

This issue was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *MITECO and the autonomous communities implement enforcement measures, in relation to infringements based on CSN's recommendations. However, certain autonomous communities have not consistently informed CSN of the outcome of their enforcement measures.*	
(1)	**BASIS: GSR Part 1 Requirement 7, para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for effective coordination of their regulatory functions, to avoid omissions or undue duplication and do avoid conflicting requirements being placed on authorized parties."*
S13	**Suggestion: The government should consider measures to ensure that the autonomous communities notify CSN of their enforcement actions.**

8.3. SUMMARY

CSN's enforcement policy and process, within the defined legal framework; together with its implementation is fully compatible with IAEA Safety Standards.

9. REGULATIONS AND GUIDES

The Spanish nuclear regulatory framework is comprised of Laws, Royal Decrees and Instructions. Laws are passed by Parliament and Royal Decrees are approved by Government. Instructions are established by CSN and published by the Government. The primary laws are the Nuclear Energy Act (Law 25/1964) and the CSN Creation Law (Law 15/1980), which set out the legal and governmental framework for nuclear and radiation safety and the clear assignment of responsibilities, the regulation of facilities and activities involving radiation risks and regulatory functions.

The function of making regulations is assigned to CSN with provisions to collaborate with foreign regulators and international organizations. This reinforces the capability of CSN to specify their own requirements and principles in conjunction with those based on valid external sources. CSN Instructions (IS) are technical requirements issued directly and independently by the CSN and are generic to all licensees. Complementary Technical Instructions (ITC) are also issued by CSN and are directed to specific sector license holders.

CSN safety guides are published by CSN and provide guidance to licensees on how to comply with requirements of the regulations. They are not legally binding and are provided for use by licensees as an accepted means to fulfil the legal requirement and are used by the CSN as the basis for carrying out their assessments in a particular area. When a licensee uses a different basis to demonstrate compliance with the regulations, this has to have been previously accepted by the CSN.

The obligation of consultation to interested parties to facilitate their participation in the elaboration of regulations is required by law. The CSN Statute explicitly requires the interaction with interested parties, including the interaction with the public for information and consultation.

The Royal Decree approving the Regulation on nuclear safety in nuclear facilities (pending Governmental approval) transposes the Directive 2014/87/EURATOM, on Nuclear Safety. Most of the requirements in this Royal Decree are captured in the CSN Instruction IS-26 that also includes the "basic nuclear safety requirements applicable to nuclear installations".

9.1. GENERIC ISSUES

The CSN process for establishing, adopting, promoting and amending regulations and guides includes a requirement to consult with interested parties in the development of Instructions and Guides. Complementary Technical Instructions are issued by CSN but are not part of the overall regulatory framework or subject to consultation. Complementary Instructions are used by CSN to direct licensees, through a legal process, to take specific action relating to the outcome regulatory review process.

CSN has a formal process for the review and revision of regulatory documents that includes the consideration of IAEA Safety Standards as one of the main references. However, it was observed that for some regulatory provisions the current IAEA standards are not fully considered and the overall process doesn’t ensure a systematic and periodic review of all regulatory documents. The IAEA standards are specifically not fully considered in the areas of Conditions of Service, Occupational Exposure (conditions of service), Medical Exposure, Radioactive Waste, Fuel Cycle Facilities and Decommissioning. This issue was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

The IRRS team was informed that there is a requirement for the independent verification of safety assessment for nuclear facilities before the submission to the regulatory body. However, the IRRS team observed that such an independent verification of safety assessments is required for radioactive facilities based upon the graded approach. The only relevant reference found relating to the need for independent verification for radioactive facilities was in a guidance document. Although the IRRS team found some

independent verifications had been completed for Category 1 radioactive facilities, these submissions were made reactively by the applicant at the request of CSN. A legal requirement should be developed to require the applicant to perform an independent verification of safety assessments for radioactive facilities, in accordance with a graded approach, before submission for regulatory review.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *While there is a formal CSN process in place for the review of regulations and guides it currently doesn't ensure that a systematic and periodic review is conducted. The cross-reference of the IAEA safety requirements and guides with the current CSN legislation (Laws, decrees, instructions and guidelines) shows that the IAEA requirements are not completely implemented.*	
(1)	**BASIS: GSG 13 Para 3.65 states that** *"The regulatory body should ensure that the regulations and guides are kept up to date and should establish procedures, within its integrated management system, for their periodic review."*
S14	**Suggestion: The regulatory authorities should consider enhancing its existing process for establishing and amending regulations and guides to include periodic and systematic reviews to ensure that the regulatory framework is maintained up to date with current international safety standards.**

The following issue was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *For some regulatory provisions the IAEA Safety Standards are not fully considered, and this was evidenced in particular in the areas of, Occupational Exposure (condition of service), Medical Exposure, Radioactive Waste, Fuel Cycle Facilities and Decommissioning.*	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
(2)	**BASIS: GSR Part 3 Requirement 34, para. 3.148 states that** *"The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging …"*
(3)	**BASIS: GSR Part 3 Requirement 41, para. 3.181 (d) states that** *"Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigated produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	medical exposure …"
(4)	**BASIS: GSR Part 3 Requirement 34, para. 3.149 (a - i and ii) states that** *"The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established:* *(a) Dose constraints, to enable the requirements of paras 3.173 and 3.174, respectively, to be fulfilled for: Exposures of careers and comforters"*
R11	**Recommendation: The regulatory authorities (Government Ministries and CSN) should comprehensively review the regulatory provisions to ensure consistency with IAEA Safety Standards and specifically in the areas of Occupational Exposure (conditions of service), Medical Exposure, Radioactive Waste, Fuel Cycle Facilities and Decommissioning.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *While there is a requirement for the independent verification of safety assessments for Nuclear Facilities, the government does not require applicants to consider performing an independent verification of safety assessment for radioactive facilities prior to submission for regulatory review and assessment.*	
(1)	**BASIS: GSR Part 1 Requirement 24, para. 4.33. states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 4 Requirement 21 states that** *"The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body."*
S15	**Suggestion: The government should consider developing a requirement for the applicant to perform an independent verification of safety assessments for radioactive facilities, in accordance with a graded approach, before submission for regulatory review and assessment.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

CSN Technical Instructions and Complementary Technical Instructions are mandatory requirements, whereas, regulatory guides provide guidance on how compliance with the safety requirements can be met. The IRRS team observed that during the development and revision of regulatory requirements (Royal Decrees, Instructions, Complementary Instructions and Guides) the graded approach is explicitly

considered and the CSN explained that for safety assessment the graded approach is applied in regulating facilities and activities.

The NPPs were authorized/licensed based on the CSN requirements and guidance document which were mainly based on the vendor regulatory framework and other considerations. Further, requirements for the submission of documents for various authorizations are contained in the Royal Decree 1836/1999 (revised in 2014). Guidance related to the format and content of some documents was issued (radiation protection manual, on-site emergency plan, quality assurance manual) but is not comprehensive.

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

Fuel cycle facilities in Spain encompass a nuclear fuel fabrication facility and temporary dry storage facilities for spent fuel. The fuel fabrication facility in Juzbado (Salamanca) has been in operation since 1985. The operator, Enusa, manufactures fuel assemblies from imported enriched uranium oxide powder and gadolinium oxide. No chemical processes are conducted in the facility.

Individual spent fuel dry temporary storage facilities (ISF´s) are located at the Trillo, José Cabrera and Ascó nuclear power plants. The Almaraz and Santa María de Garoña plants recently received a licence and the Cofrentes plant is currently in the process of licensing an ISF. The authorizations are handled as modifications to the existing operational NPP permits. The licensing of casks for the storage and transport of spent fuel is a major undertaking for CSN in the period 2018-2020.

Through the instructions IS-20 and IS-29, the CSN establishes safety requirements for spent fuel storage casks and regulates safety criteria at spent fuel and high-level radioactive waste storage facilities. There are no specific CSN instructions on fissile material and criticality safety for enriched uranium fuel fabrication facilities. CSN Safety Guides that apply to fuel cycle facilities have been published on radiation protection (GS-7.06), modifications in a nuclear fuel fabrication facility (GS-3.01), waste management plans (GS-9.03) and on quality assurance for nuclear installations (GS-10.01, GS-10.05, GS-10.07 and GS-10.08).

The IRRS team found that the IAEA safety requirement SSR-4 has not been systematically reviewed with regard to the need for changes in the regulatory provisions on criticality safety for fuel cycle facilities, see also Chapter 9.1. This is particularly evident in the areas of criticality safety programmes, operator training surveillance programmes, and emergency preparedness arrangements for sites where there are criticality hazards. In addition, the loss of criticality controls as postulated initiating events for nuclear fuel cycle facilities, identified in the SSR-4 appendix, should be included in the CSN regulations. The criticality is analysed in the nuclear facility of Juzbado in the Integrated Safety Analysis and in the Safety Analysis.

The IRRS team found that the identification of the tests to be performed as part of a facility modification proposal is required as part of the authorization application. However, a test results analysis document is not formally required, even though it is sometimes provided to meet current informal CSN regulatory practice. The provision of test results for all modifications significant to safety should be made a requirement through an update of the relevant requirements in Royal Decree 1836/1999 for all nuclear facilities.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

National policies and strategies of the waste management system

The Royal Decree 102/2014 for the responsible and safe management of spent fuel and radioactive waste develops the regulatory framework on a strategic and policy level, covering waste and spent fuel from generation to disposal. The General Radioactive Waste Plan (GRWP), further discussed in Module 1 and the ARTEMIS component of the mission, covers all types of radioactive waste.

Radioactive waste predisposal management

The CSN instruction IS-26 contains basic nuclear safety requirements applicable to nuclear installations, including the management of radioactive waste and decommissioning. CSN Safety Guides have been published on the criteria and content for radioactive waste management plans at nuclear facilities (GS-09.03), control of the LILW solidification process (GS-09.01) and on the safety assessment of surface LILW disposal facilities (GS-09.04).

The Royal Decree 102/2014 contains requirements on interdependencies to be considered at all steps in the generation and management of spent nuclear fuel and radioactive waste. The CSN safety guide GS-09.03 sets the principles for spent fuel and radioactive waste management according to its classification. Waste type classification and acceptance criteria in force for the El Cabril LILW and VLLW disposal facility are part of the operation authorization. The definition for LILW in Spain corresponds to IAEA's definition of Low-Level Waste (LLW). Nuclear and other licensees are required to sign technical and administrative acceptance specifications for their waste, with a view to its subsequent collection and management by ENRESA and the consideration of storage and disposal. These specifications have to be approved by MITECO, based on a prior CSN review and assessment report. The waste acceptance process includes procedures for radiological characterization conducted by the waste producer and checked and approved by ENRESA. The methodology for waste acceptance has been developed by ENRESA, in consultation with CSN. The process is supervised by CSN as part of the authority´s inspection procedures with two scheduled inspections per year. The same procedures and methods for waste acceptance apply with regard to decommissioning, with ENRESA being both the producer and receiver of waste. Acceptance criteria have also been an integrated part of the construction authorization for the proposed centralized spent fuel storage facility.

According to the Royal Decree 1836/1999, a radioactive waste and spent fuel management plan is required for all nuclear facilities. The safety guide GS-9.03 provides the criteria and technical bases for the plan. The waste streams are generally well characterized, and license holders are required to maintain records of waste packages generated and stored, containing the relevant information. The waste producers have a reporting obligation to ENRESA. According to the Royal Decree 102/2014, the GRWP is required to make provisions for the total Spanish inventory of spent nuclear fuel and radioactive waste, including estimates of future arisings from operational and decommissioning activities. ENRESA is responsible for maintaining the national inventory schedule and once a year has to submit a report to CSN for analysis and confirmation.

The RD 1836/1999 establishes that the disposal, recycling or reuse of radioactive substances or materials containing radioactive substances from any facility must be authorised. The decree also sets the radiological criteria applicable for the clearance of residual materials. Further, the CSN instruction IS-31 on the criteria for the radiological control of residual materials generated in nuclear facilities, specifies the technical and administrative criteria that must be met for clearance authorisation. Also, a new Ministerial Order ETU/1185/2017 regulates the authorization of conditional and un-conditional clearance of residual material from nuclear facilities.

The policy with regard to disused sealed sources is return to the manufacturer or, when this is not possible, to ENRESA. Sources received by ENRESA are either stored or disposed of at the El Cabril facility. There are no requirements or criteria for the possible clearance of the sources received by ENRESA, see also Chapter 9.6 on clearance of residual material from all fuel cycle and radioactive facilities. The polluter pays principle is applied to the producers and users of sources include authorization requirements on guarantees for the return to manufacturer or, if this is not possible, sending the source to ENRESA on a contract basis for storage and/or disposal. In the case of disused sources lacking a responsible owner, ENRESA collect the sources with charge to the existing Fund for financing the GRWP activities.

The CSN instructions IS-20 and IS-29 establish safety requirements for spent fuel storage casks and the regulatory safety criteria for spent fuel and high-level radioactive waste storage facilities. Regarding the storage of spent nuclear fuel, e.g. the individual on-site dry storages at the nuclear power plants, the facility design must allow for the retrieval of spent fuel and waste at any time for inspection, reconditioning, shipment or transfer to another waste management facility.

The establishment of a centralized temporary storage facility for spent fuel and high-level waste (CSF) is an important strategic milestone of the GRWP as it optimises the safe management of spent fuel, HLW and ILW that is now distributed to a number of facilities, allows for the release of the sites of the decommissioned nuclear facilities for other uses, without restrictions, and allows for the repatriation of wastes and materials arising from the reprocessing abroad of spent fuel. As recommended in the ARTEMIS component (R2) of the report, the Government should ensure that any delay in the implementation of the CSF does not negatively impact the safe management of spent fuel and high-level waste in Spain. A licencing process is also being conducted for a uranium recovery facility in Retortillo (Salamanca). Uranium recovery facilities are not considered nuclear facilities but "Category One radioactive facilities" in the Royal Decree 1836/1999. They are designated as "nuclear fuel cycle radioactive facilities".

Radioactive waste disposal

Regulatory requirements for the development of different types of disposal facilities mainly refer to the requirements for nuclear facilities in general. The exception being a specific CSN regulatory guide on the content of the safety case for LILW surface disposal facilities.

The post-closure period of the El Cabril disposal facilities was considered in the initial design and included in the safety case. There are specific safety rules (Basic Safety Rule 1.2) on multiple safety functions, active control measures and on the maintenance and surveillance needed to protect and preserve the passive safety barriers during operation and after closure. The CSN Safety Guide GS-9.04 includes criteria on the identification and selection of features, events and processes that may impact safety associated with the site and facility.

At the point waste disposal operations cease the El Cabril facilities will be closed in accordance with conditions set by CSN in the declaration of closure. Further guidance on the definition of surveillance and control activities to be conducted during the post closure period is given in the CSN Safety Guide SG 9.04. Before the closure of the El Cabril facility, a closure plan and a plan for institutional control covering a period of 300 years will be required including the transition to a passive state. According to the RD 102/2014, there has to be a strategy for the post closure period management, including preservation of knowledge and memory. The Decree also specifies ENRESA´s responsibility to maintain an inventory of the disposed waste after closure. Royal Decree 102/2014 also states that the State will take over the responsibility once disposal has occurred. The State also assumes the monitoring of final disposal facilities after closure, which could mean ENRESA or other state entities.

The CSN is currently developing instructions to establish safety criteria to be applied for radioactive waste disposal facilities, based on WENRA safety reference levels. An instruction on the scope and content of the safety demonstrations and studies at each stage of the life of surface disposal facilities for LILW is also in an early draft, see also chapter 9.1 on periodic and systematic reviews to ensure that the regulatory framework is maintained up to date with current international safety standards. No specific regulatory requirements have been published on the establishment of HLW or spent fuel disposal solutions. The need for developing a regulatory package with requirements on site selection, safety analysis, safety case content, etc., is apparent.

The current, unofficial, estimate is that a deep geological repository could be in operation by 2068. Initial work on repository concepts for granite and clay formations was completed by ENRESA in the 1990´s.

ENRESA is responsible for R&D on disposal but resources are mainly directed towards establishing a central storage facility. Limited progress has been made towards an active programme for a final disposal solution for spent fuel and high-level waste since the adoption of the 6th GRWP. There is no mechanism for CSN to follow, guide or provide opinion on ENRESA´s R&D work or siting activities, apart from the pending review of the updated GRWP. The regulatory authorities need to develop a regulatory approach for the step-wise licensing process. In particular, enhancing the capacity of CSN to build and maintain competence, participate in international development and research projects, prepare regulations and guides and engaging the public and stakeholders.

As recommended in the ARTEMIS component (R3) of the report, the government should complement the legal regulatory framework for establishing a deep geological repository, including clarifying roles and responsibilities at each stage of its implementation. The CSN should develop a plan for its regulatory commitment in consultation with ENRESA and other stakeholders.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

CSN has issued a range of regulations and guides to be used by duty holders conducting practices with radiation source facilities and activities. In addition to the legally binding Royal Decrees other types of legally binding instructions are published for regulating radiation source facilities and activities:

The regulations for radiation sources facilities and activities include:

- Royal Decree 1836/1999, on the regulation on nuclear and radioactive facilities,
- Royal Decree 783/2001, on the regulation on sanitary protection against ionising radiations,
- Royal Decree 1085/2009, on the regulation on installation and use of x-ray apparatus for medical diagnosis,
- Royal Decree 815/2001, on the justification of the use of ionizing radiation for the radiation protection of people subject to medical exposures,
- Royal Decree 229/2006, on the control of high activity sealed radioactive sources and orphan sources.

In addition, CSN also issues guidance for radiation sources facilities and activities including:

- IS-03 on the qualifications required to obtain recognition as an expert in protection against ionising radiations,
- IS-05 defining the values of exemption for nuclides as established in Royal Decree 1836/1999,
- IS-07 on fields of application of the radioactive facilities personnel licences,
- IS-08, on the criteria applied by CSN to request specific advice on radiation protection from the owners of the Nuclear and Radioactive Facilities
- IS-16, regulating the periods of time which documents and records of radioactive facilities must remain filed for,
- IS-28, on the technical specifications that second and third category radioactive sources must observe.

The IRRS team found that some regulations and guides for radiation source facilities and activities were not updated and fully in line with the GSR Part 3, e.g., Royal Decree 783/2001, on the regulation on sanitary protection against ionising radiations. This observation is addressed in R11 of this Module.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The Nuclear Energy Act (Law 25/1964) and the CSN Creation Law (Law 15/1980) together with the relevant Royal Decrees, cover the regulation of decommissioning activities. The principle of minimization of waste generation is defined in the Law of 1964 (art 38) as well as in the Royal Decree 102/2014 (art 3).

The Ministerial Order ETU/1185/2017 regulating the clearance of the waste materials generated in nuclear facilities contains clearance criteria. This binding order also guarantees the traceability of the materials up to delivery to the final managers and requires that the information will be archived and made available to CSN. For Category II and III radioactive facilities, clearance values are mentioned in Ministerial Order ECO/1449/2003

While some regulatory provisions have been made, the IRRS team found that no general applicable guidance on the application of clearance is available. For example, for radioactive fuel cycle facilities no clearance values are available in a specific instruction or other legally binding documents.

There is a need to establish guidance on 'clearance' applicable to all types of facilities and activities and including disused sealed sources. The guide should include information on the practical implementation of the clearance process and cover the need for clearance decisions by CSN to be communicated to licensees, registrants and stakeholders.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *While some regulatory provisions have been made, CSN has not established a specific procedure governing the clearance of sources, materials and objects from regulatory control, and which encompasses all types of facilities and activities. In addition, clearance of disused sealed sources after decay is not considered.*	
(1)	**BASIS: GSR Part 3 Requirement 8, para. 3.12 states that** *"The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies."*
S16	**Suggestion: CSN should consider establishing regulatory provisions on clearance, applicable to all types of facilities or activities and communicated to authorized parties and stakeholders.**

CSN explained to the IRRS team that, related to decommissioning, two important regulatory documents had been developed but still needed approval:

- draft Instruction on basic requirements for the safe decommissioning of nuclear facilities that are applicable during the design, construction and operation phases.
- draft Instruction on the safe decommissioning, and where appropriate, safe closure of nuclear and radioactive fuel cycle facilities.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

The transport of radioactive material is subject to the regulatory framework for Nuclear Safety and Radiation Protection, which is mainly based on Law 25/1964 and Law 15/1980 and describes CSN responsibilities in the area of Transport. This concerns approval and validation of package designs and inspection and authorization of transport. These tasks also include collaboration with other authorities including MITECO and the Autonomous Communities.

In addition, the transport of radioactive material is also subject to the regulatory framework of the transport of dangerous goods (Class 7), through which the IAEA Transport Regulations SSR-6 are implemented in Spain (ADR, RID, IMDG-Code, ICAO-TI). Collaboration of CSN with other authorities, including the Ministry of Public Works, is also necessary within this field.

It was found that the responsibilities of all competent authorities are clearly specified by Law and that the cooperation between CSN and the other relevant authorities is based on legal requirements (MITECO) or specified by Memorandum of Understanding, including specific Protocols (Ministry of Public Works), or by Local Agreements (Autonomous Communities, for inspection tasks only). CSN confirmed that the cooperation arrangements generally work well.

Spain is a contracting party to the IAEA Conventions and other International agreements, relating to the transport of dangerous goods including radioactive material (Class 7). The international regulations apply to the different modes of transport respectively ADR (road), RID (rail), IMDG Code (sea) and ICAO TI (air). The transport requirements of the IAEA Regulations SSR-6 are also fully implemented into these international regulations.

The CSN has developed a comprehensive set of instructions and guidance to support the user to apply the IAEA Transport Regulations correctly. The topics of these guides and instructions have been derived from inspection results of CSN, which gave rise to potential non-compliances with the Regulations. Together with the comprehensive CSN - Webpage presentation “Transport of radioactive material” which covers all main criteria and aspects of the transport regulations which must be considered to carry out a transport of radioactive material in Spain an excellent guidance, training and information material for all users and interested parties has been created. The IRRS team considers this integrated and interlinked guidance and information material as a good performance of CSN in this field.

It can be concluded that the Regulations and Guides for safe transport of radioactive material in Spain are in compliance with the requirements of SSR-6 for all modes of transport.

9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The regulation of occupational exposure is addressed in the legal framework for nuclear safety (Nuclear Law, Royal Decrees) and is supported by explanatory or guidance material such as technical instructions and guides. Examples of these are; RD 783/2001, RD 413/1997, GS 7.06 and IS-01, which define the format and content of the individual radiological monitoring document (Radiological Passport).

Management of the dose records at the national level

As required by GSR Part 1, Req.35, the CSN is managing a National Databank on Dose Records as required in the “CSN organizational and operational organization, Vers.3”. This data bank contains the records of the legal doses which are provided by the authorized Dosimetry Services. These records are used by the CSN to detect possible trends in the dose distribution and to perform studies on the dose distribution in the different areas. The data is also used by CSN for the presentation of radiation dose records within its annual report to the Parliament.

Compliance by workers

Royal Decree 413/1997 - Art 6. estates that all off-site workers are obliged to collaborate with those responsible for radiological protection including their own company and the licensee in respect of ensuring their protection against ionizing radiations. The CSN SG 1.12 on "Practical application of optimization of radiation protection in nuclear power plant operations" establishes the responsibilities of workers, both licensee and contractors" in respect of occupational exposure. Royal Decree 783/2001 Art 37 requires the workers involved in more than one activity or installation to inform of this circumstance to ensure that a complete picture of individual dosimetry is maintained.

Arrangements under the radiation protection programme

The Radiation Protection Manual describes the measures taken for the radiation protection of the workers in nuclear installations and radioactive facilities.

The general principles for the protection of workers are provided in the Royal Decree 783/2001 art 15: prior evaluation of the working conditions, classification of the working places (controlled and supervised areas, art.16 and 18), classification of exposed workers (Cat. A and Cat. B in RD 783/2001 Art.20), individual monitoring (art.27 to 29) and workplace monitoring (art.26 and 31). Local rules and procedures and personal protective equipment are described in SG 7.06 (3.10, 3.11, 3.15).

Regulatory provisions for appropriate information, instruction and training of persons working in controlled areas are presented in RD 783/2001, art.21 covering workers, persons in training, students and special circumstances for women in the condition of pregnancy and lactation.

Protection of workers in existing exposure situations

Provisions for the protection of workers in existing situations are given in RD 783/2001 art.62 and a graded approach is implemented.

9.9. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

Regulations on for medical exposure

The Spanish regulatory framework for medical exposure control comprises of Laws 15/1980, 14/1986, Royal decrees 1132/1990, 1836/1999, 1976/1999, 1841/1997, 1566/1998, 1085/2009, 220/1997, 783/2001, 183/2008, and Instructions CSN IS-28. Regulatory Guides regarding with radiation protection of the occupational and public exposure involving the use of the radiation sources for medical uses are described in sections 9.8 and 9.10.

The implementation of regulatory framework is under the responsibilities of CSN and other Competent Autonomous Community Health Authorities according to their competences. However, the IRRS team observed that in comparison with the IAEA Safety Standards the following requirements are not included in the Spanish regulatory framework: (This is covered in R11 of this Module).

- Requirements to ensure that relevant parties are authorized to assume their roles regarding dose constraints for careers, comforters and volunteers participating in a programme of biomedical research.
- Requirements on minimizing of unintended or accidental medical exposure related to human errors.
- Requirements for radiodiagnosis facilities on prompt investigation any of the following unintended or accidental medical exposure.
- Requirements for the registered users and licensees to record and report the corrective actions to prevent the recurrence of any unintended or accidental medical exposures.

- Requirements for radiodiagnosis facilities to submit a written record in case of a significant unintended or accidental medical exposure to the regulatory body, and to the relevant health authority.

The values of reference levels regarding diagnostic (radiodiagnosis and nuclear medicine) are established in the Annex of the Royal Decree 1976/1999 and Royal Decree 1841/1997. However, the IRRS team was informed that the values are obsolete and there are no reference level values for several explorations based on the results of two National Projects supported by CSN and performed in named DOMNES and DOPOES respectively for Nuclear Medicine and Radiodiagnosis. In addition, both National Projects were adopted by the European Community as published in http://ddmed.eu/. This is covered in R11 of this Module.

9.10. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The Nuclear Energy Act (Law 25/1964) and the CSN Creation Law (Law 15/1980) together with the relevant Royal Decrees cover the regulation of public exposure to ionising radiation. Dose limits for the public are defined in the regulations.

According to art 51 of RD783/2001, all discharges of effluents and radioactive waste into the environment requires the authorization of MITECO. Discharge limits, surveillance requirements and conditions for release are included in the license. For radioactive facilities, the license may contain limits for the controlled discharge of liquid radioactive effluents from the site.

Article 62 of RD 783/2001 requires title holders of occupational activities where natural sources of radiation are present, to evaluate the radiation exposure to workers and members of the public and to report to the competent authorities.

Reference levels for drinking water are set in Royal Decree 314/2016, transposing European Directive 2013/51. Water suppliers are responsible for completing the necessary surveillance and control plans to ensure compliance with the reference levels, under the supervision of the regional health authorities. The IRRS team was informed that for food and feed notification levels are developed taking into account a dose criterion and specific pathways and scenarios. The notification levels serve as a trigger for further investigation and characterization processes. The IRRS team was informed that Spain has no reference levels regarding the use of construction materials. However, according to the CSN, such reference levels (in compliance with Article 75 of EU Directive 2013/59) will be defined in the updated Regulation on Sanitary Protection against Ionizing Radiation (currently under review). This issue was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Spain has not established Reference Levels in its current regulations for public dose exposure due to radionuclides in construction materials.*	
(1)	**BASIS: GSR Part 3 Requirement 51, para. 5.22 states that** *"The regulatory body or other relevant authority shall establish specific reference levels for exposure due to radionuclides in commodities such as construction materials, food and feed, and in drinking water, each of which shall typically be expressed as, or be based on, an annual effective dose to the representative person that generally does not exceed a value of about 1 mSv."*
R12	**Recommendation: The government should establish Reference Levels for public dose exposure due to radionuclides in construction materials.**

9.11. SUMMARY

Spain has a mature legislative and regulatory framework for the protection of people and the environment from the harmful effects of ionising radiation in nuclear energy, radiation sources, transport, decommissioning and radioactive waste management. The framework is generally compatible with the IAEA Safety Standards.

However, this IRRS mission has identified a number of areas for further improvement to the legislative and regulatory framework in the following areas:

- enhancing the existing process for establishing and amending regulations to ensure that the regulatory framework is maintained up to date with current international safety standards;
- developing a requirement for the independent verification of safety assessments for radioactive facilities;
- establishing regulatory provisions on clearance, applicable to all types of facilities or activities and communicated to authorized parties and stakeholders;
- establishing Reference Levels for public dose exposure due to radionuclides in construction materials.

10. EMERGENCY PREPAREDNESS AND RESPONSE REGULATORY ASPECTS

10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS

The Royal Decree 1836/1999 approving the Regulation on Nuclear and Radioactive Facilities requires an on-site emergency plan and that the Spanish Nuclear Council (CSN) has the following responsibilities:

- Establishing regulations and guides for emergency preparedness and response (EPR) arrangements;
- Verifying compliance of the on-site emergency arrangements, against the regulatory requirements, before commencing operation of the facility or before conducting the activity, and afterwards, during the lifetime of the facility or conduction of the activity;
- Review and assessment of the documentation elaborating an operator's emergency arrangements during the licensing process;
- Inspections of EPR arrangements;
- Evaluating some of the exercises conducted by the operating organizations;
- Ensuring that the operating organization's emergency arrangements are coordinated with those of other organizations and integrated with contingency plans and security plans established for nuclear security purposes; and,
- Inspection, assessment, control and adoption of as many prevention and protection actions as necessary during emergency situations that originate in unregulated activities and facilities.

The CSN process for review and approval of an operating organization's onsite emergency preparedness plan (PEI) is primarily conducted utilizing guidance documents 1.3 Guidance for Onsite Nuclear Emergency Plans and 1.9 Guidance for Conducting Drills and Exercises of the PEI. A licensee is able to propose an alternative approach to this guidance for CSN's consideration during the approval process. CSN conducts an analysis of the submitted PEI and, if found to be adequate, provides its analysis and recommendation for approval to MITECO. Once the approval is provided by MITECO to the licensee, the licensee has 30 days to implement the approved PEI.

CSN EPR requirements are found in letters, instructions, guidance and complementary instructions. Historically, documents from CSN communicating some EP requirements to licensees included letters identifying what is needed to be contained in PEIs to meet the guidance. Other documents, such as instructions, may contain an item specific to EPR even though the instruction is not directly related to the EPR programme. For example, CSN's Instruction IS-28, Annex I, I.7, states that the PEI contain requirements for licensee radiation workers to participate in emergency drills every two years as a practical application of their training, where appropriate. CSN can issue complementary instructions (ITCs) to require licensees to implement immediate changes to their PEI. For instance, as a result of the Fukushima-Daichii event in March 2011, CSN issued five complementary instructions to each licensee which included requirements regarding emergency preparedness.

CSN considers the legally binding requirements for each licensee's emergency preparedness programme are established as a result of the PEI approval process. The Nuclear Energy Act, Law 25/1964, of April 29th, 1964 and as amended, provides that the approval of a licensee's emergency plan by MITECO, based upon a CSN report, establishes the licensee's site-specific PEI as their legally binding set of EPR requirements. Therefore, any enforcement actions taken with regard to a licensee's PEI are issue against the PEI. Notably, CSN has yet to issue an enforcement action against a licensee's PEI; although, CSN has issued minor findings to a licensee identifying the PEI as the requirement.

CSN has identified the need to reinforce EPR requirements for licensees by developing an instruction. This item is identified in CSN's Action Plan. However, CSN has not identified in its Action Plan the need to develop associated guidance documents describing acceptable methods to meet the requirements contained within the instruction for use by the operating organizations. A draft instruction has been developed taking into account the CSN Safety Guides, the letters and ITC (Complementary Technical Instructions) after Fukushima accidents sent to every licensee, the set of requirements established in the limits and conditions of the licensee's operating authorizations, and the experience gained over the years. It is a compendium of instructions and requirements of nuclear emergency management.

This instruction is to provide for improvements in emergency management as follows:

- Reinforce onsite Emergency Response Organization (OER)
- Emergencies communication systems: more autonomy and redundancy
- Establishment of a new Emergency Support Centre near Madrid
- Establishment of a new Emergency Management Alternative Centres at every site
- Coordination between on-site emergency Direction and off-site emergency Direction in order to trigger the Direct Ventilation System
- Rewording and revised definitions of nuclear events at NPP´s
- New guides to manage severe and extend accidents elaborated by licensees
- New areas to allow helicopter landing
- Safety Areas at every site to storage post Fukushima equipment such as Diesel Generators, high and low-pressure pumps and hoses, and electrical cables with quick connections
- Drills in sites with two units are scheduled considering that both units could be affected

All of these items are contained in previously issued complementary instructions to every licensee, mainly after the Fukushima accident.

This issue was acknowledged by the CSN and an action was included in the action plan resulting from the self-assessment performed prior to the IRRS mission.
The CSN 2018 Annual Work Plan, Annex 1, item 20 states that a multi-year project to develop requirements for planning and response to nuclear power plant emergencies is to be performed in 2018-2019. Draft 5 of the instruction was completed in June 2018.

The Royal Decree 1546/2004, of June 25, 2006, approving the Basic Nuclear Emergency Plan requires coordination between on-site and off-site EPR arrangements. For this reason, the required coordination established in the PEIs makes it clear that the licensee must inform, as soon as possible, of the timing and the amount of radiological activity which could be released. Additionally, CSN and licensee field monitoring teams coordinate their sample activities to maximize efficiency and emergency worker radiological safety.

The Royal Decree 1086 issued on December 4, 2015, "Physical Protection of Nuclear Material and Facilities, and Radioactive Sources," was consistent with the international commitments, "Amendment of the Convention of Physical Protection of Nuclear Material" of IAEA and United Nations Resolutions.

Consequently, nuclear power plant licensees have trained offsite responders on the PEI and the site physical protection capabilities.

The CSN organizational structure has a Deputy Direction of Security and Emergency Preparedness (CSN/SEP) that has four areas, three of those directly devoted to emergency preparedness and response. The four areas and their responsibilities are:

1. Emergency Planning and Preparedness (PLEM) – evaluation and inspection of EPR arrangements of nuclear facilities (including on-site emergency plans) and of EPR regulation in general;
2. Emergency Operations Coordination (COEM) – maintain the CSN's capabilities to respond to an emergency and inform and coordinate actions, where applicable, with other off-site organizations;
3. Intervention and Preparation Emergency Responders (IPAE) – plan and schedule exercises and training activities that maintain availability of the CSN's capabilities to respond to a nuclear or radiological emergency; and,
4. Nuclear Security (SEFI) – oversee security matters and enforce security requirements.

The task of assessment and inspection of EPR arrangements of radioactive facilities and transportation is performed directly by the Deputy Directions that also perform the licensing tasks of such installations and activities.

As a result, hazards identified and potential consequences of an emergency that are assessed, provide a basis for establishing arrangements for preparedness and response for a nuclear or radiological emergency. These arrangements are commensurate with the hazards identified and the potential consequences of an emergency. The hazard assessment performed constitutes the basis of a graded approach to EPR. Consequently, when a nuclear power plant enters the decommissioning process, there is a commensurate reduction in the radiological risk to public health and safety than an operating reactor.

As CSN licenses nuclear power plant transitions to decommissioning a new hazard analysis is required to grant the authorization for decommissioning. This authorization establishes a graded approach for onsite EPR arrangements. Currently, the process of changing the emergency preparedness offsite response is initiated by the Ministry of Interior. The Ministry requests CSN to provide an analysis indicating whether the offsite radiological response capabilities are needed. Subsequently, CSN taking into account the previously mentioned hazard analysis that is required for the authorization for decommissioning, will then inform the Ministry about the reduction of risk to public health consistent with a graded approach to emergency preparedness during the decommissioning process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although CSN has issued some requirements on EPR and considers an authorized party's approved emergency plan as legally binding requirements, CSN has identified that the reinforcement of EPR requirements for nuclear operating organizations via an instruction is convenient to improve the Spanish regulatory framework for EPR. Currently, CSN has developed a Draft 5 Instruction in support of this effort. Additionally, CSN did not identify in its Action Plan the need to develop associated guidance documents.*	
(1)	**BASIS: GSR Part 7 para. 4.12 states that** *"The regulatory body is required to establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based [7]. These regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization. (see also paras 1.12 and 4.5)."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S17	**Suggestion: CSN should consider finalizing a consolidated and comprehensive set of EPR regulatory provisions for authorized parties upon which CSN can base its regulatory judgements, decisions, and actions. Further, CSN should develop associated guidance documents describing acceptable methods to meet the requirements for use by the authorized parties.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *During decommissioning, the Ministry of Interior initiates the process to change the emergency preparedness offsite response. Subsequently the Ministry requests CSN to provide an analysis indicating whether the offsite radiological response capabilities are needed to provide for the protection of public health and safety., CSN assesses the licensee's hazard analysis previously required for decommissioning authorization, in order to answer the request according to the graded approach and the reduction of the risk to public health and safety, but the CSN does not inform the results of the assessment until the request of the Ministry of Interior. .*	
(1)	**BASIS: GSR Part 7 para. 4.18 states that** *"Hazards shall be identified and potential consequences of an emergency shall be assessed to provide a basis for establishing arrangements for preparedness and response for a nuclear or radiological emergency. These arrangements shall be commensurate with the hazards identified and the potential consequences of an emergency."*
(2)	**BASIS: GSR Part 7 para. 4.26 states that** *"The government through the regulatory body shall ensure that operating organizations review appropriately and, as necessary, revise the emergency arrangements (a) prior to any changes in the facility or activity that affect the existing hazard assessment and (b) when new information becomes available that provides insights into the adequacy of the existing arrangements. Footnote 11: Examples of such changes and available information include the movement of irradiated nuclear fuel to a new location, projected flooding, and information on storms or other meteorological hazards."*
(3)	**BASIS: GSR Part 7 para 5.38 states, in part that** *"For facilities in Category I or II, arrangements shall be made for effectively making decisions on and taking urgent protective actions, early protective actions and other response actions off the site in order to achieve the goals of emergency response, on the basis of a graded approach and in accordance with the protection strategy."*
S18	**Suggestion: CSN should consider informing the Ministry of Interior, prior to its request for an assessment by CSN, of changes to public risk identified during the decommissioning phase, commensurate with the hazards identified and the potential offsite consequences of an emergency.**

10.2. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS

Royal Decree 1836/1999, December 3, 1999, approving the Regulation on Nuclear and Radioactive Facilities states that nuclear and radioactive facilities, in order to obtain an operating license, must perform a hazard analysis as well as a safety assessment (article 20.a.e for nuclear facilities and article 38.1.b for radioactive facilities), and must also develop an on-site Emergency Plan that considers potential accident conditions (article 20.d for nuclear facilities, and article 38.1.e for radioactive facilities).

CSN guidance document GS-1.03, "Nuclear power plant emergency plan" describes, in considerably more detail, acceptable methods to address the above-mentioned Royal Decree.

The guidance clearly prescribes responsibilities of the on-site emergency management (including decision makers) to include the necessary coordination with off-site decision-makers of nuclear or radiological emergencies. On-site emergency management informs the appropriate offsite authorities of the timing and the amount of radiological activity which could be released during an emergency. An example of the on-site to offsite coordination of activities include that CSN and licensee field monitoring teams coordinate their sample activities to maximize efficiency and emergency worker radiological safety.

With regard to defining "emergency workers," response organization plans, royal decrees and CSN complementary instructions have varying: definitions for the personnel; actions to be taken when reaching prescribed dose limits; and, levels of detail. Additionally, response plans, Royal Decrees or CSN complementary instructions, either characterize these personnel into two groups or three groups. For instance, the CSN internal technical procedure manual PT.VI.28, "Emergency Management," Section 5.3, states that Group 1 personnel have a dose limit corresponding to a threshold of manifestation of mild deterministic effects, that is, 500 mSv of effective dose and stipulates that those personnel performing actions are voluntary and must not include pregnant women. It also provides details on dosimetry alarm setpoints and consideration for worker replacement. In contrast, the CSN complementary instruction (CSN/ITC/SG/ALO/12/01, 4.1.6) issued in March 2012 following the Fukushima-Daichii event, directed each licensee to characterize OER personnel into two different groups based upon limitations on dose levels received during the emergency. However, the ITC Group 1 description does not address the exclusion of pregnant women and provides no additional detail on dosimetry alarm setpoints or consideration for worker replacement. Other instances of emergency worker inconsistencies are found in Royal Decree (RD) 1564/2010 Annex 5 and offsite emergency response plans for the local jurisdictions (e.g., PENCA).

Royal Decree 1546/2004, of June 25th, approving the Basic Nuclear Emergency Plan provides direction on the organizational and hierarchical structure for the offsite Nuclear Emergency Plan (PLABEN). The Royal Decree states that the PLABEN should allow for the performance of the following basic functions:

- Determination, management and coordination of the measures to protect the population and other emergency response actions;
- Implementation of protective measures and application of other actions in the affected areas; and,
- Information for the affected population, the public Administration organizations concerned and the media during an emergency.

Included in the offsite response organizational structure is an Information and Communications office for each nuclear site. The office is to be located at the headquarters of the Delegation or Sub Delegation of the Government of the province in which the nuclear power plant is located. The office is staffed by government personnel in those groups. The functions of the Information and Communications are: 1) to put together and distribute the information and recommendations to be transmitted to the population; and, 2) to centralize and coordinate general information on the emergency to be provided to the population actually affected and make this information available to the media. Licensees are not required to have a role in communication with the public or media, nor to coordinate any information with the CSN Information and Communications

Office which may be provided to the public or media. In converse, the PLABEN does not state that any information provided to the public regarding plant operations be coordinated with the licensee.

An ITC was issued in November 2017 to each nuclear power plant regarding a modification on the process for changes made to emergency preparedness plans. The ITC stated that only changes identified within the ITC were required to be submitted for approval prior to being implemented. Those items not included on the list were considered to be minor changes, and if implemented, would most probably not result in a reduction in safety. As such, the process does not consider that an evaluation is needed to determine if minor changes could possibly result in a reduction in safety.

CSN issued five complementary instructions (ITCs) to require licensees to implement immediate changes to their PEI as a result of the Fukushima-Daichii event in March 2011. All licensees have completed the required actions identified in the instructions regarding EPR. It is seen as good performance that CSN has facilitated agreements between the emergency military unit and the operating organizations to provide equipment, resources and response actions during an emergency that is in addition to the ITC Fukushima-Daichii related EPR requirements. These items include supplying pumps and generators, equipment to remove debris, and transportation for operating organizations' emergency response staff.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Onsite and Offsite response organization plans, Royal Decrees and CSN complementary instructions have varying and inconsistent provisions, as well as the level of detail, definitions for emergency workers and actions to be taken when reaching prescribed dose limits.*	
(1)	**BASIS: GSR Part 3 Requirement 45, para.4.12 states that** *"The government shall establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers, which shall be implemented by response organizations and employers."*
(2)	**BASIS: GSG-2 para. 4.1 states that** *"An emergency worker is a person having specified duties as a worker in response to an emergency, who might be exposed while taking actions in response to the emergency. Emergency workers may include those employed by registrants and licensees as well as personnel from response organizations, such as police officers, firefighters, medical personnel, and drivers and crews of evacuation vehicles.*
(3)	**BASIS: GSR Part 7 para. 5.51. states that** *"The operating organization and response organizations shall determine the anticipated hazardous conditions, both on the site and off the site, in which emergency workers might have to perform response functions in a nuclear or radiological emergency in accordance with the hazard assessment and the protection strategy"*
S19	**Suggestion: The Government and CSN should consider revising the regulatory provisions for on-site and off-site response activities to provide: a consistent definition for emergency workers, dose limits based upon emergency response activities, and actions to be taken if prescribed dose limits are exceeded.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *During EPR, CSN does not require authorized parties to communicate with the public and media. Additionally, any information the government provides to the public and media during EPR is not coordinated with the authorized parties.*	
(1)	**BASIS: GSR Part 7 para. 4.12 states that** *"The regulatory body is required to establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based [7]. These regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization. (see also paras 1.12 and 4.5)."*
(2)	**BASIS: GS-G-2.1, para. 6.4 states that** *"The second general operational concept is that arrangements should be made to promptly provide useful and coordinated information to the public via the news media. This should include arrangements to ensure that the public statements of the operator, local officials and national officials all provide a consistent message to the public. While this could be accomplished by other means, in this concept of operations it is accomplished by establishing, as soon as possible, a single location as the public information centre (see Appendix VIII). In addition, in all cases the public should be provided with a plain language explanation of the risks to them, the actions they can take to reduce the risks and the actions being taken to ensure that people are safe and their interests are being protected. It should be recognized that this applies to any event perceived as an emergency by the public or the media."*
(3)	**BASIS: GSR 7 Requirement 2, para. 4.10 states that** *"The government shall establish a national coordinating mechanism to be functional at the preparedness stage, consistent with its emergency management system, with the following functions: (i) To coordinate effective communication with the public in preparedness for a nuclear or radiological emergency.*
(4)	**BASIS: GSR 7 Requirement 13, para. 5.70 states that** *"Arrangements shall be made to ensure that information provided to the public by response organizations, operating organizations, the regulatory body, international organizations and others in a nuclear or radiological emergency is coordinated and consistent, with due recognition of the evolutionary nature of an emergency."*
R13	**Recommendation: The Government should enhance provisions to ensure coordination among operating organizations, as well as response organizations and the regulatory authorities, to ensure that the government provides prompt and useful information to the public and media during a nuclear and radiological emergency. The coordination of the communication should be exercised and evaluated.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Changes in the Emergency plan identified in the complementary instruction CSN/C/SG/ALO.17/01 that are considered to be major changes are required to be submitted to CSN prior to implementation. However, CSN does not require operating organizations to conduct an analysis to justify its conclusion that a change is minor.*	
(1)	**BASIS: GSR Part 7 para. 4.12 states that** *"The regulatory body is required to establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based [7]. These regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization. (see also paras 1.12 and 4.5)."*
(2)	**BASIS: GSR Part 7 para. 4.26 states that** *"The government through the regulatory body shall ensure that operating organizations review appropriately and, as necessary, revise the emergency arrangements (a) prior to any changes in the facility or activity that affect the existing hazard assessment and (b) when new information becomes available that provides insights into the adequacy of the existing arrangements. Footnote 11: Examples of such changes and available information include the movement of irradiated nuclear fuel to a new location, projected flooding, and information on storms or other meteorological hazards."*
S20	**Suggestion: CSN should consider enhancing provisions to require operating organizations to perform an analysis to justify when a change is minor.**

10.3. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS

Royal Decree 1836/1999 states that CSN's responsibilities includes ensuring that the licensee's emergency arrangements are coordinated with those of other organizations and integrated with contingency plans and security plans established for nuclear security purposes. Additionally, the monitoring from the CSN Emergency Centre (Salem) of annual licensees' exercises, which is also considered a training activity for the CSN Emergency Response Organization, allows for the assessment of certain features of emergency notification, communication, and licensee's response, including coordination with off-site emergency decision takers.

Regarding transport, consignors and consignees of radioactive materials are commonly nuclear or radioactive facilities subject to authorization. To obtain that authorization, these companies have to present an Emergency Plan or Emergency Procedure, including emergency response for the transport activity. The CSN reviews and assesses this plan. The implementation of the Emergency Plan and procedures are subject to periodic inspection. In the case of carriers, they must be registered in a registration database maintained by MITECO. In order to be registered, these companies have to present a Radiation Protection Programme (RPP) which includes an Emergency Plan. The control of the implementation and modifications of the emergency procedures are conducted by periodic inspections.

CSN conducts inspections of the adequacy of licensees' emergency preparedness programs using two inspection procedures: 1) PT.IV.260, Maintaining Emergency Preparedness; and, 2) PT.IV.261, Inspection of Emergency Preparedness and Exercises. These inspections are conducted by both CSN staff from Madrid offices and the Resident Inspectors.

PT.IV.260 is conducted on a biennial basis. The inspection procedure objectives are to review:

- emergency plan changes and whether they diminish the effectiveness of the PEI;
- emergency organization response and augmentation;
- emergency facilities and equipment;
- initial and requalification training of emergency response personnel;
- the identification and correction of weaknesses resulting from exercises; and
- independent or internal audits of the PEI and implementing procedures.

PT.IV.261 is conducted on an annual basis or as soon as practical following a declared emergency event. The inspection procedure objectives are to:

- review the different constitutive phases of a simulated emergency using the PEI;
- verify the results of the exercise and the adequacy of the corrective measures or improvements identified in previous inspections; and,
- verify the licensee's emergency response after a declared emergency event.

The task of assessment and inspection of EPR arrangements of radioactive facilities and transportation is performed directly by the Deputy Directions that perform the licensing tasks of such installations and activities. CSN identified the need to develop a plan to conduct emergency exercises for the transport of radioactive material on a periodical basis. The IRRS team noted that such a plan is now available. With regard to radioactive facilities, according to the graded approach, requirements for EPR arrangements are stated within GS-7.10, "Radioactive facilities' onsite emergency plans," and the Instruction IS-18, the 2nd of April 2008, on the criteria applied by the CSN to require licensees of radioactive facilities to report radiological events and incidents.

During the conduct of emergency preparedness inspections, if an inspector identifies an item of interest, it is screened utilizing CSN procedure PA.IV.204, "Screening Inspection Results" to determine if the finding has sufficient relevance, in terms of its significance for the risk, to be documented, as well as to establish the process for its subsequent treatment. If the finding has sufficient relevance, it enters the process of determination of significance (known by the acronym in English SDP, Significance Determination Process). For emergency preparedness, the procedure PT.IV.310, "Process of determination of significance for safety of the SISC emergency preparedness pillar" would be used. This procedure identifies eight functional areas of emergency preparedness and assesses safety significance based upon a graded approach to safety. The graded approach identifies three of the functions as having more significance with regard to safety (these have the designation FS) and whether the finding was found during a real event. The eight functions are:

- F1 Emergency Response Organization
- FS2 Emergency Classification
- FS3 Emergency Notification
- FS4 Emergency evaluation and monitoring
- F5 Response Means
- F6 Response Measures
- F7 Recovery of the NPP
- F8 Maintenance of response capacity of the PEI

10.4. ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

CSN has an emergency organization complementary to its normal working organisation. The operational structure of the CSN OER is headed by the President who is responsible for decisions. The emergency organization includes the technical and logistics units, in accordance with the CSN Emergency Action Plan (PAE) established specifically for emergency situations. The PAE is activated depending on the level of severity of the emergency. The CSN OER operates from an Emergency Room (Salem) that is staffed continuously by two individuals and has a stand-by emergency team capable of responding to an emergency situation in less than one hour. The CSN Salem is equipped with communications systems and assessment tools to aid in the assessment of: the level of off-site response that should be activated; the evolution of the accident and potential consequences; and, the public protection measures that should be implemented. The CSN response capabilities are complemented with external support provided by specialized public and private entities.

An area of good performance is in addition to the CSN Salem located in Madrid, a Back-up Emergency Centre (Salem 2) located at the Headquarters of the Emergency Military Unit (UME) with similar capabilities as Salem. An agreement between CSN and UME ensures that Salem 2 is available for CSN OER staffing in the event that Salem is not accessible or inhabitable. The activation of Salem 2 is embedded within the scope of the PAE for continuing CSN activities (Plan de continuidad de actividades del CSN). When activated, Salem 2 can perform all of the essential functions of emergency response that would be conducted in Salem. Additionally, CSN conducts an emergency exercise annually in Salem 2 to ensure functionality and to identify areas for improvement.

The PAE contains a programme of exercises and drills of internal, national and international scope that allows the operability of its technical capacities to be checked periodically and the appropriate improvements to be made. Additionally, the PAE includes a training plan for CSN emergency response staff. Internal CSN instruction IPAE-2 describes the structure, content, schedule and evaluation of training programs for the OERRE. Basically, IPAE-2 establishes three levels of training:

- Level 1, for all CSN Staff with basic concepts in emergencies
- Level 2, for CSN OER with advanced concepts in emergencies
- Level 3, for each specific group defined in the CSN OER with very technical specific training.

This multi-year training programme is executed in annual training programs for each CSN emergency response group defined in the CSN ORE. Annually, each group specific training needs and specific objectives and every year this information is compiled in an annual training programme. The Deputy Direction for Emergencies and Security is responsible for the programme execution, level of compliance and results evaluation.

However, IPAE-2 is not very detailed regarding mandatory training requirements for ORE position qualification and continuing training, evaluation of training activities, and how to improve training activities. Additionally, attendance at ORE position training is not mandatory. Thus, not all ORE staff receives refresher training and may not be provided the necessary skills to adequately perform their position functions. This issue was identified by CSN in the Action Plan after the self-assessment for the IRRS Mission. This is particularly true as response activities are improved over the years. (refer to Module 3, S5).

CSN has various functions with regard to its emergency response activities. These functions encompass four different areas:

1. Standards Development
2. Planning
3. Implementation
4. Activation

The activities of the OER during an actual emergency situation take priority over any other CSN activity. Consequently, whenever emergency response is necessary, all and any of CSN's resources shall be made available to the ORE and any other activity being performed shall immediately be suspended. Most notably, it is clearly stated in the PAE (Section 4.1) that the ERO acts independently of the regulatory and control function assigned to the CSN.

Finally, the CSN emergency management process is regularly audited according to the CSN management system.

10.5. SUMMARY

Overall, CSN oversight of emergency preparedness programs and response capabilities provides for the adequate protection of public health and safety. The government and CSN can enhance their emergency preparedness oversight and response capabilities by:

- Reinforcing Spanish regulatory framework on EPR by finalizing the process of approving and issuing the new CSN Instruction on EPR Management and developing the guidance documents accordingly.
- informing the Ministry of Interior of changes to public risk identified during the decommissioning phase and the potential offsite consequences of an emergency.
- revising the regulatory provisions for on-site and off-site response activities to provide: a consistent definition for emergency workers, dose limits based upon emergency response activities, and actions to be taken if prescribed dose limits are exceeded.
- ensuring coordination among operating organizations, as well as response organizations and the regulatory authorities, to ensure that the government provides prompt and useful information to the public and media during a nuclear and radiological emergency.
- enhancing provisions to require operating organizations to justify when a change is minor.

IRRS/ARTEMIS SPAIN 2018 REVIEW TEAM

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APPENDIX II - MISSION PROGRAMME

<table>
<tr><th>Time</th><th>SAT</th><th>SUN 14</th><th>MON 15</th><th>TUE 16</th><th>WED 17</th><th>THU 18</th><th>FRI 19</th><th>SAT 20</th><th>SUN 21</th></tr>
<tr><td>9:00-9:15</td><td rowspan="15">Arrival of IRRS Team Members</td><td rowspan="4">IRRS Team Building:
• Self-introduction
• Refresher training</td><td rowspan="4">Entrance Meeting</td><td rowspan="4">Interviews</td><td rowspan="4">Visits</td><td rowspan="4">Interviews</td><td rowspan="4">Visits</td><td rowspan="4">Interviews</td><td rowspan="4">Visits</td><td rowspan="4">DTC writes introductory parts</td><td></td><td rowspan="4">• Discussing and improving Draft Report
• Cross-Reading
• TL, DTL, TC and DTC read everything</td><td rowspan="5">Free day, Social Tour</td><td rowspan="5">Reading, Cross-reading of the Report</td></tr>
<tr><td>09:15-11:15</td><td>Policy Issues Discussions</td></tr>
<tr><td>11:15-12:00</td><td>TM write Report
TL and DTL review introductory part</td></tr>
<tr><td></td><td>Draft text to TL</td></tr>
<tr><td>12:00-12:30</td><td rowspan="2">Lunch with Host</td><td colspan="7">Standing lunch</td></tr>
<tr><td>12:30-13:00</td><td rowspan="2">Lunch</td></tr>
<tr><td>13:00-14:00</td><td rowspan="3">Interviews</td><td rowspan="3">Interviews</td><td rowspan="3">Visits</td><td rowspan="3">Interviews</td><td rowspan="3">Visits</td><td rowspan="3">Interviews if needed</td><td rowspan="3">DTC writes introductory parts</td><td></td><td rowspan="5">Finalisation of the Draft Report</td><td rowspan="3">Lunch at Los Galayos Restaurant</td><td rowspan="3"></td></tr>
<tr><td>14:00-15:00</td><td>IRRS-ARTEMIS Plenary Meeting</td></tr>
<tr><td>15:00-16:00</td><td rowspan="2">Initial IRRS Team Meeting:
(may start, at the latest, at 4pm for logistical reason):
• Mission logistics
• Discussion of first impressions
• Closing</td><td rowspan="2">Secretariat edits the report
Preliminary Draft Report Ready</td><td rowspan="2">Cross-reading by TM</td></tr>
<tr><td>16:00-17:00</td><td colspan="2">Written preliminary findings delivered</td><td>TM write Report</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting</td><td>Daily Team Meeting</td><td>Daily Team Meeting: Discussion of findings</td><td>Daily Team Meeting</td><td colspan="2">Daily Team Meeting</td><td></td><td></td></tr>
<tr><td>18:00-18:30</td><td>IRRS - ARTEMIS Coordination Meetings</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>18:30-20:00</td><td rowspan="2"></td><td rowspan="2">Free</td><td colspan="5">Writing of the report</td><td rowspan="2">TM Read Draft</td><td rowspan="2">IRRS Admin edits the report</td><td rowspan="2"></td><td rowspan="2"></td></tr>
<tr><td>19:00-20:00</td><td colspan="5">Writing of the report / IRRS - ARTEMIS Coordination Meetings*</td></tr>
<tr><td>20:00-21:00</td><td rowspan="2"></td><td rowspan="2">Dinner</td><td colspan="7">Dinner</td><td></td><td></td></tr>
<tr><td>21:00 -…</td><td colspan="5">Writing of the report</td><td></td><td>IRRS Admin edits the report</td><td></td><td></td></tr>
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<table>
<tr><th></th><th>MON 22</th><th>TUE 23</th><th>WED 24</th><th>THU 25</th><th>FRI 26</th></tr>
<tr><td>9:00-10:00</td><td rowspan="2">Discussion of Recommendations, Suggestions and Good Practises with counterparts by module</td><td rowspan="2">Cross-Reading of the Report
TL, DTL, TC and DTC read everything
Finalisation</td><td>Briefing of the Senior IAEA Manager
Common read through and finalisation of the Report by the IRRS team</td><td rowspan="2">Host reads Draft Report and Executive Summary</td><td>Submission of the Preliminary Report</td></tr>
<tr><td>10:00-12:00</td><td>Submission of the Draft to the Host</td><td rowspan="2">Exit Meeting
Press Conference
Publication of Press Release</td></tr>
<tr><td>12:00-13:00</td><td>Standing lunch</td><td>Standing lunch</td><td>Standing Lunch</td><td>Standing Lunch</td></tr>
<tr><td>13:00-14:00</td><td>Policy Discussions if necessary</td><td rowspan="3">Discussion of the Report by the IRRS team</td><td rowspan="3">TC, DTC prepare Executive Summary and exit presentation</td><td rowspan="3">Host reads Draft Report</td><td rowspan="3">TL finalises Executive Summary and Exit Presentation</td><td rowspan="3">IAEA Press Officer and TC draft the Press Release</td><td>Written comments provided by the Host

Team meeting to discuss and resolve Host comments</td><td rowspan="4">Departure</td></tr>
<tr><td>14:00-17:00</td><td>Individual discussions of Recommendations, Suggestions and Good Practises with counterparts</td><td>Plenary (Team + Host) to discuss Host comments and finalize the report</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting</td><td>Discussion of IRRS-ARTEMIS Executive Summary and delivery to the Host</td><td>Finalisation of the press release and of the Preliminary Report</td></tr>
<tr><td>18:00-19:00</td><td colspan="2" rowspan="2">IRRS Admin updates Report</td><td colspan="3">Free</td></tr>
<tr><td>19:00-20:30</td><td colspan="3"></td></tr>
<tr><td>20:30-21:30</td><td>Dinner</td><td>Social Dinner /</td><td colspan="2" rowspan="2">Dinner</td><td rowspan="2"></td></tr>
<tr><td>21:30 -…</td><td>IRRS Admin updates Report</td><td>IRRS Admin finalises Report</td></tr>
</table>

- Meeting with the Secretary of State of Energy: 17 October at 10am, MITECO Headquarter
- Meeting with the CSN Board: 18 October at 10am, CSN Headquarter
- A shuttle service is provided for two weeks. Departures: 8.30 at Meliá Hotel / 18.30 (1st w) -18.00 (2nd w) at CSN Hq, including morning Sat-20. Sat-20 afternoon and Sun-21 not available.
- Meeting with Unions: 17 October at 14:00 – 15:00 – Meeting room on the 3rd floor
- IRRS – ARTEMIS Coordination Meeting at the Hotel, attended only by: IRRS and ARTEMIS Team leads, Johan Anderberg, Masahiro Aoki (if necessary)

APPENDIX III – IRRS MISSION COUNTERPARTS

	IRRS Experts	CSN Lead Counterpart	CSN Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Masahiro Aoki	Enrique García-Fresneda	Isabel Villanueva Jacobo Zegri
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Gabriela Siraky	Enrique García-Fresneda	Alfredo de los Reyes Isabel Villanueva
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Minna Tuomainen	Antonio Munuera	María Fernanda Sánchez
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Darja Slokan-Dusic	Ivan Recarte	Rafael Cid
5.	**AUTHORIZATION**		
	Olivier Lareynie	Cristina Les	Alejandro de Santos José María Balmisa Carmen Álvarez
6.	**REVIEW AND ASSESSMENT**		
	Naveed Maqbul	José Ramon Alonso	Arturo Pérez

	IRRS Experts	CSN Lead Counterpart	CSN Support Staff
7.	**INSPECTION**		
	Scott Morris	Cristina Les	César Gervás
8.	**ENFORCEMENT**		
	Graeme Thomas	Victoria Méndez	David García
9.	**REGULATIONS AND GUIDES**		
	Gerhard Roos	Cristina Villalba	Ana Hernández Manuel Peña
10.	**EMERGENCY PREPAREDNESS AND RESPONSE REGULATORY ASPECTS**		
	Robert Kahler	Miguel Calvín Alfredo Mozas	José Manuel Martín Antonio Ortiz Juan Pedro García
	RADIATION SOURCES		
	Helena Janzekovic	Javier Zarzuela	Dolores Aguado María Luisa Ramírez
	FUEL CYCLE		
	Johan Anderberg	Fernando Zamora	Luis Gascó Rubén Fernández
	RADIOACTIVE WASTE MANAGEMENT		

	IRRS Experts	CSN Lead Counterpart	CSN Support Staff
	Johan Anderberg	María Jesús Muñoz Juan José Montesinos	Julia López
	TRANSPORT		
	Frank Nitsche	Fernando Zamora	Manuel García
	DECOMMISSIONING		
	Walter Blommaert	José Luis Revilla	Susana Solís
	OCCUPATIONAL RADIATION PROTECTION		
	Pascal Deboodt	Teresa Labarta Javier Zarzuela	Ignacio Amor
	CONTROL OF MEDICAL EXPOSURE		
	Flavia Cristina Da Silva Teixeira	Carmen Álvarez	María Luisa Ramírez
	PUBLIC PLANNED AND EXISTING EXPOSURE		
	Walter Blommaert	María Jesús Muñoz Marta García-Talavera	José Ignacio Serrano Carmen Rey María José Barahona Sofía Luque María Teresa Sanz

APPENDIX IV - RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

AREA	R: Recommendation S: Suggestion GP: Good Practice	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	S1	Suggestion: The Government should consider making provisions to maintain the staffing level of CSN at the level necessary to achieve the safety objective and commensurate with the fees paid by the authorized parties.
	R1	Recommendation: The Government should establish mechanisms to ensure that the responsibilities assigned to the Competent Autonomous Community Health Authorities are effectively implemented.
	S2	Suggestion: The Ministry of Health and CSN should consider taking immediate steps toward applying the MOU for collaboration, signed in November 2010.
	S3	Suggestion: CSN should consider establishing cooperation agreements with other competent authorities regarding the management of contaminated sites
	R2	Recommendation: The Government should take immediate steps towards making decisions regarding updates to the GRWP such that the plan can inform decision making to ensure the continued safe and sustainable management, including interim storage and disposal, of radioactive waste in Spain.
2. GLOBAL NUCLEAR SAFETY REGIME	-	-
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S4	Suggestion: CSN should consider engaging in a discussion with government, to obtain the flexibility to adjust its organisational structure.
	S5	Suggestion: CSN should consider enhancing its training activities by establishing a more systematic approach to training and by considering formal qualification for certain positions.

	S6	**Suggestion: CSN should consider creating a consolidated and comprehensive Human Resource Plan.**
	R3	**Recommendation: The regulatory authorities should require the relevant authorised parties to inform the public about the possible radiation risks associated with their facilities and activities, in accordance with a graded approach.**
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**S7**	**Suggestion: CSN should consider establishing a process to identify, assess and implement organisational changes.**
	R4	**Recommendation: CSN should establish a record retention schedule to define the required retention times for each type of records, the associated responsibilities, the record format and support, and the record storage location.**
	R5	**Recommendation: CSN should develop and implement provisions to conduct regular self-assessments of its management system.**
	S8	**Suggestion: CSN should consider conducting regular assessments of its safety culture.**
5. AUTHORIZATION	**R6**	**Recommendation: The Government should revise the legal and regulatory framework to comply with the requirements of GSR Part 3 for strengthening the control over radiation sources facilities and activities.**
	S9	**Suggestion: CSN should consider establishing regulatory provisions requiring the authorized parties, as a prerequisite for the transfer of responsibility of the facility, to ensure the transmission of institutional knowledge.**
	S10	**Suggestion: CSN should consider updating the regulatory provisions to add a requirement for licensees to submit a final decommissioning report as part of the application for license termination, including a description of the contents of the final decommissioning report.**
	R7	**Recommendation: The Government should assign the responsibility for all approval types according to the IAEA Transport Regulations and identify the**

		competent authority for notification regarding the first shipment of an approved package in Spain.
	R8	**Recommendation: The Government should update the dose limits for the lens of the eyes to ensure full compliance with the IAEA Safety Standards.**
6. REVIEW AND ASSESSMENT	**S11**	**Suggestion: CSN should consider updating the regulatory provisions to require licensees to submit an initial and final decommissioning plan for review and approval and describe the contents of such plans.**
	R9	**Recommendation: In accordance with a graded approach, CSN should arrange for assessments of the radiation dose to members of the public associated with the transport of radioactive material to ensure that the system of protection and safety complies with the Basic Safety Standards.**
	GP1	**Good Practice: The CSN Transport Database goes beyond the normal scope of databases used in transport by linking together information applicable to different areas of the compliance assurance programme like inspection results, approval certificates, fabricated and used packaging, non-compliances, events during transport which are available for all consignors and carriers in Spain. It provides an excellent tool for the competent authority to improve and facilitate the implementation of its compliance assurance programme.**
	R10	**Recommendation: The government should ensure that a national radon action plan be completed and approved, comprising coordinated actions to reduce activity concentrations of radon in existing and future buildings, and assign responsibilities for establishing and implementing this action plan.**
7. INSPECTION	**S12**	**Suggestion: CSN should consider enhancing the inspection program to include verification of the adequacy of the documentary evidence that each packaging used for spent fuel storage and/or transport is manufactured in compliance with the approved design specifications.**
8. ENFORCEMENT	**S13**	**Suggestion: The government should consider measures to ensure that the autonomous communities notify CSN of their enforcement actions.**

9. REGULATIONS AND GUIDES	**S14**	**Suggestion: The regulatory authorities should consider enhancing its existing process for establishing and amending regulations and guides to include periodic and systematic reviews to ensure that the regulatory framework is maintained up to date with current international safety standards.**
	R11	**Recommendation: The regulatory authorities (Government Ministries and CSN) should comprehensively review the regulatory provisions to ensure consistency with IAEA Safety Standards and specifically in the areas of Occupational Exposure (conditions of service), Medical Exposure, Radioactive Waste, Fuel Cycle Facilities and Decommissioning.**
	S15	**Suggestion: The government should consider developing a requirement for the applicant to perform an independent verification of safety assessments for radioactive facilities, in accordance with a graded approach, before submission for regulatory review and assessment.**
	S16	**Suggestion: CSN should consider establishing regulatory provisions on clearance, applicable to all types of facilities or activities and communicated to authorized parties and stakeholders.**
	R12	**Recommendation: The government should establish Reference Levels for public dose exposure due to radionuclides in construction materials.**
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	**S17**	**Suggestion: CSN should consider finalizing a consolidated and comprehensive set of EPR regulatory provisions for authorized parties upon which CSN can base its regulatory judgements, decisions, and actions. Further, CSN should develop associated guidance documents describing acceptable methods to meet the requirements for use by the authorized parties.**
	S18	**Suggestion: CSN should consider informing the Ministry of Interior, prior to its request for an assessment by CSN, of changes to public risk identified during the decommissioning phase, commensurate with the hazards identified and the potential offsite consequences of an emergency.**
	S19	**Suggestion: The Government and CSN should consider revising the regulatory provisions for on-site and off-site response activities to provide: a consistent**

		definition for emergency workers, dose limits based upon emergency response activities, and actions to be taken if prescribed dose limits are exceeded.
	R13	**Recommendation: The Government should enhance provisions to ensure coordination among operating organizations, as well as response organizations and the regulatory authorities, to ensure that the government provides prompt and useful information to the public and media during a nuclear and radiological emergency. The coordination of the communication should be exercised and evaluated.**
	S20	**Suggestion: CSN should consider enhancing provisions to require operating organizations to perform an analysis to justify when a change is minor.**

APPENDIX V - REFERENCE MATERIAL PROVIDED BY CSN

[1] International Conventions, Treaties

- *Country Report Joint Convention (2018) and Convention on Nuclear Safety (2015)*
- *Brussels Supplementary Convention*
- *Convention for the protection of the marine environment of the North East Atlantic*
- *Convention on access to information, public participation in decision making environmental matters*
- *Convention on Assistance in the case of a nuclear accident or radiological emergency*
- *Convention on Early Notification of a nuclear accident*
- *Convention on environmental impact assessment in transboundary context*
- *Convention on nuclear safety*
- *Convention on the physical protection of nuclear material*
- *Convention on third party liability in the field of nuclear energy*
- *International Convention for the suppression of acts of nuclear terrorism*
- *Joint Convention on the safety of spent fuel management and on the safety of radioactive waste*
- *Treaty on the non-proliferation of nuclear weapons*

[2] European Union Directives, Regulations and Agreements

- *Commission Implementing Regulation 2016*
- *Commission Regulation 302.2005 Euratom Safeguards*
- *Council Directive 96/ 29/ EURATOM*
- *Council Directive 2206/117/EURATOM*
- *Council Directive 2009/71/EURATOM*
- *Council Directive 2011/70/EURATOM*
- *Council Directive 2013/70/EURATOM*
- *Council Directive 2014/87/EURATOM*
- *Council Regulation on Shipments of radioactive substances between Member States nº 1439/93*
- *Council Regulation Instrument for Nuclear Safety Cooperation nº 237/2014*
- *Council Regulation Permitted levels radiological emergency nº 52/2016*
- *Directive 2008/68/EC on inland transport of dangerous goods*
- *European Agreement concerning the International Carriage of Dangerous Goods by road.*

[3] National Laws

- *Law 14/1999 Governing Public Pries and Fees for services rendered by CSN*
- *Law 15/1980 creating the nuclear safety council*
- *Law 25/1964 Nuclear Energy Act*

[4] Regulatory Standards. Royal Decrees

- *Royal Decree 1546/2998 approving the Basic Nuclear Emergency Plan*
- *Royal Decree 413/1997 on the operational protection of offsite workers running the risk of exposure to ionising radiations due to their interventions in the controlled zone*
- *Draft of Spanish Royal Decree approving the Regulation on nuclear safety in nuclear facilities*
- *Royal Decree approving the Regulation on installation and use of X ray apparatus for medical diagnosis*
- *Royal Decree 1836/1999 approving the Regulation on Nuclear and Radioactive facilities*

- *Decree 2177/1967 approving the regulation on nuclear risk cover*
- *Royal Decree 783/2001 which approves the Regulation on sanitary protection against ionising radiations*
- *Royal Decree 102/2014 on the responsible and safe management of spent nuclear fuel and radioactive waste*
- *Royal Decree 1440/2010 approving the Statute of the Nuclear Safety Council*

[5] CSN Instructions

- *IS 01 defines the format and content of the individual radiological monitoring document (Radiological Passport)*
- *IS 02 on documentation relating to refuelling activities at light water NPP*
- *IS 03 on the qualifications required to obtain recognition as an expert in protection against ionizing radiations*
- *IS 04 regulating the transference, filing, and custody of the documents relating to the radiation protection of the workers, the general public and the environment prior to the transference of the license ownership of the nuclear power plants for dismantling and decommissioning*
- *IS 05 defining the values of exemption for nuclides*
- *IS 06 defining training programmes on basic and specific radiation protection matters*
- *IS 07 on fields of application of the radioactive facilities personnel licenses*
- *IS 08 on the criteria applied by CSN to request specific advice on radiation protection from owners of the nuclear and radioactive facilities*
- *IS 09 establishing the criteria to be applied for the systems services and procedures of physical protection for nuclear facilities and materials*
- *IS 10 establishing the criteria for reporting events to nuclear safety Council by the NPP*
- *IS 11 on licenses for operating personnel of NPP*
- *IS 12 defining the qualification and training requirements of non-licensed staff and non-licensed off-site personnel of NPP*
- *IS 13 on the radiological criteria for the release of Nuclear Facilities sites*
- *IS 14 on the CSN resident inspection at NPP*
- *IS 15 on the requirements for monitoring the effectiveness of maintenance at the NPP*
- *IS 16 regulating the periods of time which documents and records of radioactive facilities must be remain filed for*
- *IS 17 on the recognition of training courses and programmes for personnel that manage the operation of or operate equipment in X ray facilities for medical diagnosis and the accreditation of the personnel of said facilities*
- *IS 18 on the criteria applied by CSN to demand from licenses of radioactive facilities the reporting of radiological events and incidents*
- *IS 19 on the requirements of the nuclear facilities management system*
- *IS 20 establishing safety requirements relating to spent fuel storage casks*
- *IS 21 on the requirements applicable to modifications at NPP*
- *IS 22 regarding safety requirements for the management of the ageing and long-term operation of NPP*
- *IS 23 on in-service inspection at NPP*
- *IS 24 regulating the filing and periods of retention of the documents and records of Nuclear facilities*
- *IS 25 on criteria and requirements on the performance of probabilistic safety assessments and their applications for NPP*
- *IS 26 on the basic nuclear safety requirements applicable to nuclear installations*

- *IS 27 on general nuclear power plant design criteria*
- *IS 28 on the technical specifications that second and third category radioactive facilities must observe*
- *IS 29 on safety criteria at spent fuel and high-level radioactive waste storage facilities*
- *IS 30 on the requirements of the fire protection programme at NPP*
- *IS 31 on the criteria for the radiological control of residual materials generated in nuclear facilities*
- *IS 32 on Plant Technical specifications of NPP*
- *IS 33 on the radiological criteria for the protection against exposure to natural radiation*
- *IS 34 on criteria in relation to radiation protection measures, the notification of non-conformities, the availability of people and means during emergencies, and load surveillance during the transport of radioactive material*
- *IS 35 relating to the treatment of design modifications of radioactive material transport packages accompanied by certificates demonstrating their Spanish origin and of the physical or operational modifications performed by the consignor of a package on the packaging used*
- *IS 36 on emergency operating procedures and the management of severe accidents at NPP*
- *IS 37 on the analysis of design basis accidents at NPP*
- *IS 38 on the training of persons involved in the transport of radioactive material by road*
- *IS 39 regarding the control and monitoring in the manufacturing of packages for the transport of radioactive material*
- *IS 40 regarding documents that must be provided when requesting authorization for commercialization or providing technical assistance of appliances, equipment, and accessories that contain radioactive material or are generators of ionizing radiations*
- *IS 41 requirements on physical protection of radioactive sources*
- *IS 42 criteria on notification of certain events to the CSN of the transport of radioactive material*

[6] CSN Safety Guides

- *GS-01-10 Periodic Safety Reviews NPP*
- *GS-03-01 Modifications to facilities manufacturing nuclear fuels*
- *GS-05-03 Control of the hermeticity of sealed sources*
- *GS-04-12 Accreditation of training courses for supervisors and operators of radioactive facilities*
- *GS-06.04 Documentation to request authorizations for the transport of radioactive materials*
- *GS-07.01 Technical and administrative requirements for individual personal dosimetry services*
- *GS-07.03 Foundations for the establishment of Radiological Protection Technical Services*

[7] Other CSN documents

- *ARM IRRS Transport of radioactive material*
- *CSN Safety culture safety policy*
- *CSN report to the Parliament 2016*
- *CSN Strategic Plan 2017-2022*
- *CSN Code of ethics*
- *Framework for the CSN´s inspection functions*
- *CSN Annual work plan 2018*
- *CSN Organization and operations manual 2018*
- *R&D Plan 2016-2020*

[8] Other

- *6th General Radioactive waste plan*
- *US NRC Regulation Guide 1.143*

[9] SARIS Module Reports

- *IRRS SARIS Report SPAIN*
- *IRRS ARM Summary report Spain*
- *IRRS ACTION PLAN SPAIN*
- *IRRS Policy issues SPAIN*

APPENDIX VI - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. **IAEA SAFETY STANDARDS SERIES No. SF-1** – Fundamental Safety Principles
2. **IAEA SAFETY STANDARDS SERIES No. GSR PART 1 (Rev. 1)** – Governmental, Legal and Regulatory Framework for Safety
3. **IAEA SAFETY STANDARDS SERIES No. GSR PART 2** – Leadership and Management for Safety
4. **IAEA SAFETY STANDARDS SERIES No. GSR PART 3** – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
5. **IAEA SAFETY STANDARDS SERIES No. GSR PART 4 (Rev. 1)** – Safety Assessment for Facilities and Activities
6. **IAEA SAFETY STANDARDS SERIES No. GSR PART 6** – Decommissioning of Facilities
7. **IAEA SAFETY STANDARDS SERIES No. GSR PART 7** – Preparedness and Response for a Nuclear or Radiological Emergency
8. **IAEA SAFETY STANDARDS SERIES No. SSR-2/1** – Safety of Nuclear Power Plants: Design
9. **IAEA SAFETY STANDARDS SERIES No. SSR-2/2** – Safety of Nuclear Power Plants: Commissioning and Operation
10. **IAEA SAFETY STANDARDS SERIES No. SSR-4** – Safety of Nuclear Fuel Cycle Facilities
11. **IAEA SAFETY STANDARDS SERIES No. SSR-5** – Disposal of Radioactive Waste
12. **IAEA SAFETY STANDARDS SERIES No. SSR-6** – Regulations for the Safe Transport of Radioactive Material
13. **IAEA SAFETY STANDARDS SERIES No. TS-R-1** – Regulations for the Safe Transport of Radioactive Material
14. **IAEA SAFETY STANDARDS SERIES No. GSG-6** – Communication and Consultation with Interested Parties by the Regulatory Body
15. **IAEA SAFETY STANDARDS SERIES No. GSG-12** – Organization, Management and Staffing of the Regulatory Body for Safety
16. **IAEA SAFETY STANDARDS SERIES No. GSG-13** – Functions and Processes of the Regulatory Body for Safety
17. **IAEA SAFETY STANDARDS SERIES No. GS-G-2.1** – Arrangements for Preparedness for a Nuclear or Radiological Emergency

18. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.1 -** Application of the Management System for Facilities and Activities

19. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.2 -** The Management System for Technical Services in Radiation Safety

20. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.3 -** Assessment of Occupational Exposure Due to External Sources of Radiation

21. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.4 -** Building Competence in Radiation Protection and the Safe Use of Radiation Sources

22. **IAEA SAFETY STANDARDS SERIES No.** SSG-25 **-** Periodic Safety Review for Nuclear Power Plants

23. **IAEA SAFETY STANDARDS SERIES No. SSG-50 –** Operating Experience Feedback for Nuclear Installations

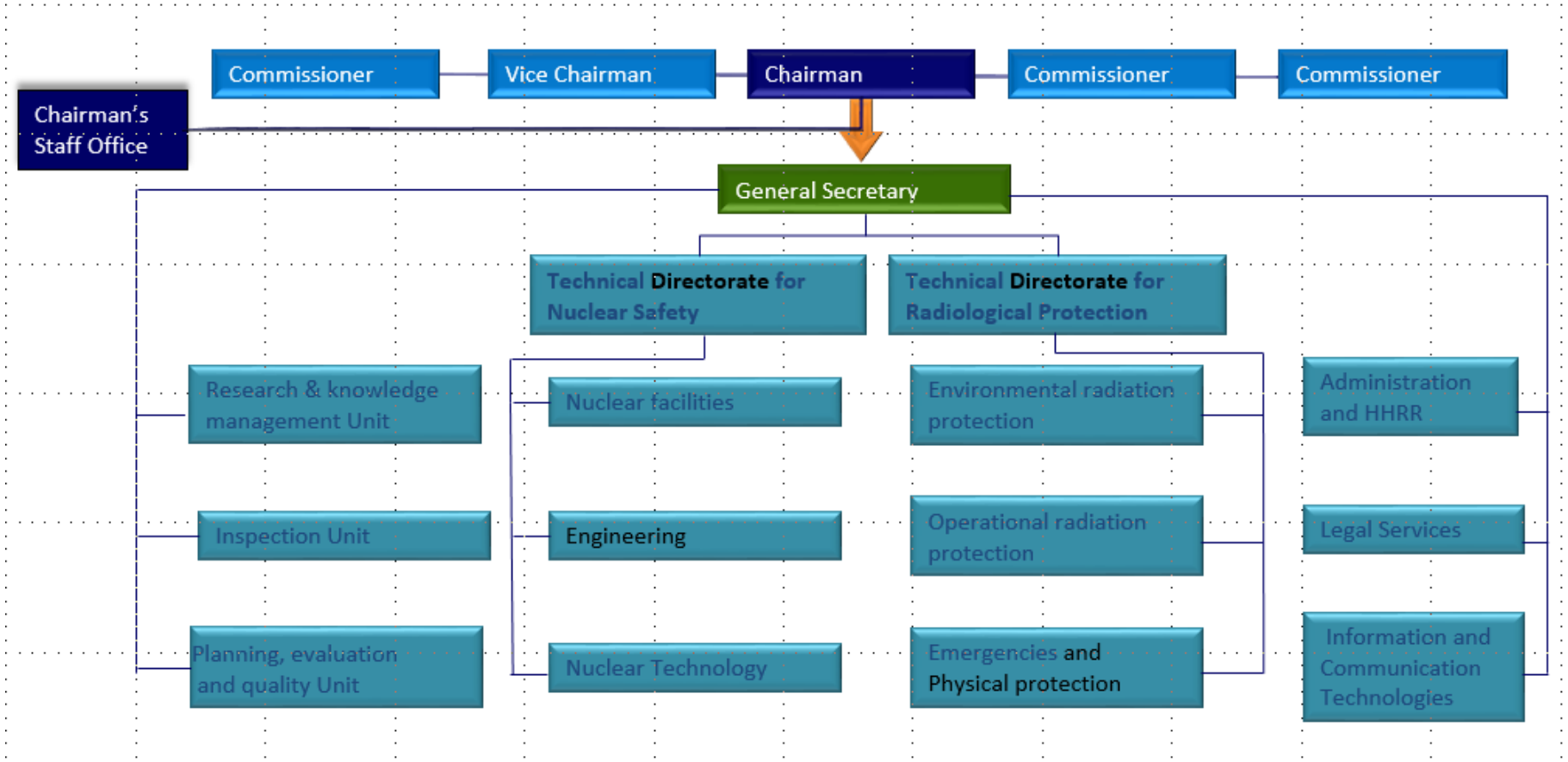
24. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

25. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Generic Assessment Procedures for Determining Protective Actions during a Reactor Accident, IAEA-TECDOC-955, IAEA, Vienna (1997)

26. **INTERNATIONAL ATOMIC ENERGY AGENCY -** General Safety Guide SGS-7 Occupational Radiation Protection

27. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Specific Safety Guide -46 Radiation Protection and Safety in Medical uses of Ionization Radiation

APPENDIX VII – CSN ORGANIZATIONAL CHART



CONTENTS – ARTEMIS (COMPONENT II)

I. OBJECTIVE AND SCOPE

The ARTEMIS review provided an independent international evaluation of the Radioactive Waste and Spent Fuel Management Programme of Spain, requested in line with the obligations of the *Waste Directive*.

The ARTEMIS review, organized by the Department of Nuclear Safety and Security and the Department of Nuclear Energy of the IAEA, performed against the relevant IAEA Safety Standards and proven international practice and experiences with the combined expertise of the international peer review team selected by the IAEA.

The ARTEMIS review assessed, as requested by the *Waste Directive*, the overall programme for the management of all types of radioactive waste and spent fuel in Spain.

II. BASIS FOR THE REVIEW

D) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Spain, a preparatory meeting for the Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation (ARTEMIS) and Integrated Regulatory Review Service (IRRS) combined Mission was conducted from 25 to 26 January 2018. The preparatory meeting was carried out by the appointed Team Leader Mr Victor McCree, Deputy Team Leader for IRRS Mr Carl-Magnus Larsson, Francois Besnus, Deputy Team Leader for ARTEMIS and the IRRS IAEA Team representatives, Mr David Senior, Section Head, Mr Jean-René Jubin Team Coordinator for IRRS, Mr Gerard Bruno Team Coordinator for ARTEMIS, Mr Ronald Jimenez Pacheco Deputy Team coordinator for IRRS, and Mr Clement Hill Deputy Team coordinator for ARTEMIS. The National Counterparts were represented by Mr Javier Dies (CSN), Ms Rosario Velasco (CSN), Mr Manuel Rodriguez (CSN), Mr Antonio Munuera (CSN), Ms M. Fernanda Sanchez (CSN), Mr E. García Fresneda (CSN), Ms Isabel Villanueva (CSN), Mr Ivan Recarte (CSN), Mr Diego Encinas (CSN), Mr Jacobo Zegrí (CSN), Mr José M. Redondo (MINETAD), Mr Jesús Tardón (MINETAD), Ms Irene Dovale (MINETAD), Mr Jaime de Ponga (MINETAD), Mr Santiago Blanes (MINETAD), Mr Mariano Navarro (ENRESA), Ms Elena Vico (ENRESA), Ms Nuria Prieto (ENRESA) and Mr Carlos Ruiz de la Sierra (MAEC).

The ARTEMIS mission preparatory team had discussions regarding:

- the Terms of Reference for the ARTEMIS review of the Spanish programme to fulfil obligations from article 14(3) of the Waste Directive; and
- the relevant detailed aspects for organization and conduct of the review.

IAEA staff presented the ARTEMIS principles, process and methodology. This was followed by a discussion on the work plan for the implementation of the ARTEMIS review in Spain in October 2018.

Mr José M. Redondo (Deputy Director General, MITECO) and Mr Alvaro Rodriguez (Technical Director ENRESA) were appointed as host Liaison Officers for the ARTEMIS mission and designated IAEA point of contact.

Spain provided IAEA with the Advance Reference Material (ARM) for the review at the end of July 2018.

B) REFERENCES FOR THE REVIEW

The guidelines for the ARTEMIS review service and the responses to the self-assessment questionnaire were used as the basis for the review together with the ARM and materials presented during the mission and associated discussions. The complete list of IAEA publications used as the basis for this review is provided in Appendix D.

C) CONDUCT OF THE REVIEW

The initial ARTEMIS Review Team meeting took place on Sunday, 14 October 2018 in Madrid, directed by the ARTEMIS Deputy Team Leader Mr François Besnus and the ARTEMIS Team Coordinator Mr Gerard Bruno. The Deputy Team Coordinator, Mr Clément Hill supported his respective leads.

The host Liaison Officers for the ARTEMIS mission Mr José M. Redondo and Mr Alvaro Rodriguez were present at the initial Review Team meeting, in accordance with the ARTEMIS guidelines, and presented logistical arrangements planned for the mission.

The entrance meeting was held on Monday, 15 October 2018, with the participation of CSN, MITECO and ENRESA senior management and staff. Opening remarks were made by Mr. Fernando Marti Scharfhausen, President of the Consejo de Seguridad Nuclear (CSN), Mr Victor McCree, IRRS/ARTEMIS Team Leader and Mr David Senior IAEA Representative. Mr Jose Manuel Redondo (MITECO) and Mr Alvaro Rodriguez (ENRESA) gave an overview of the radioactive waste management programme in Spain. The Team Coordinators of the IRRS - ARTEMIS Combined mission presented the arrangements in place to ensure and effective coordination between both IRRS and ARTEMIS Teams.

During the ARTEMIS mission, a review was conducted for all review topics within the agreed scope with the objective of providing Spanish authorities with recommendations and suggestions for improvement and, where appropriate, identifying good practice.

The Review Team performed its review according to the mission programme given in Appendix B.

The preliminary ARTEMIS reporting meeting was held in ENRESA premises on Wednesday, 24 October 2018. Opening remarks were presented by the President of ENRESA Mr José Luis Navarro Ribera and Mr Victor McCree, IRRS/ARTEMIS Team Leader, and were followed by the presentation of the results of the mission by the ARTEMIS Deputy Team Leader Mr François Besnus.

1. NATIONAL POLICY AND FRAMEWORK FOR RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT

1.1. NATIONAL POLICY

Spanish position

Spain has chosen to embark on a nuclear power in the early1960s. Presently, the nuclear energy and waste management policy in Spain has resulted in developing a relatively large nuclear programme which comprises operational and shut nuclear power plant sites, spent nuclear fuel storages, a number of radioactive waste management facilities, including a solid radioactive waste disposal facility, and two major facilities in project to achieve full availability of technical solutions for the sustainable management of the higher level waste (special waste, waste from reprocessing abroad and high activity disused sealed radioactive sources) and spent fuel: Centralized Storage Facility (CSF) and Deep Geological Disposal facility (DGD). More detailed information on the programme is given in chapter 2.

In accordance with the provisions of article 38 bis of the Law 25/1964 (on nuclear energy), read together with article 5 of the Royal Decree 102/2014 (on the responsible and safe management of spent nuclear fuel and radioactive waste), the Government is mandated with responsibility to establish the policy on the management of radioactive waste, including spent nuclear fuel, and the dismantling and decommissioning of nuclear facilities, through the adoption of the General Radioactive Waste Plan (GRWP).

The GRWP is intended to address the strategies, necessary actions and technical solutions to be developed in the short, medium and long terms, aimed at ensuring the adequate management of radioactive waste and spent fuel, the dismantling and decommissioning of nuclear and, where appropriate, radioactive facilities and associated activities, including the economic and financial measures required to carry them out. Article 6 of the Royal Decree 102/2014 prescribes the content of the GRWP.

In accordance with current regulations, the GRWP is required to be periodically reviewed based on the scientific and technical developments, the know-how acquired as well as the recommendations, lessons and good practices resulting from peer review processes. The GRWP is the reference framework for national strategies on the management of spent fuel and radioactive waste.

Whilst reprocessing of spent fuel was contemplated in the early years, this practice was stopped in 1982 except for Vandellós I NPP spent fuel, which was sent for reprocessing in France. Since 1983 the spent nuclear fuel management policy in Spain has followed the open cycle with no planned reprocessing. This has led Spain to consider spent fuel as radioactive waste that must, as all other radioactive waste produced in the country, be disposed of safely in appropriate facilities.

The policy for disused sealed radioactive sources is based on the principle of return to supplier. However, if return to supplier is not possible, sources meeting the waste acceptance criteria are disposed of at the El Cabril Disposal Facility for low and intermediate level radioactive waste or stored with the intention of disposal in the planned Deep Geological Disposal facility.

With respect to decommissioning of all nuclear power plants with light water reactors and radioactive facilities, immediate and complete dismantling is the preferred approach. The aim of the decommissioning is to achieve either full or restricted release of the site from further regulatory control. The management of radioactive waste, including spent nuclear fuel, and the dismantling and decommissioning of nuclear facilities, in Spain constitutes an essential public service which is assigned to Empresa Nacional de Residuos Radiactivos S. A. S.M.E. M.P. (ENRESA) under Article 38 bis of the Nuclear Energy Act (Law 25/1964). ENRESA is also mandated to act as the licensee of operation relating the dismantling and

decommissioning of nuclear facilities. Decommissioning of radioactive facilities is under the responsibility of the licence holder and, where necessary, ENRESA will assist.

In line with the principle of reuse and recycling, clearance of material is permitted, subject to compliance with the Order ETU/1185/2017, which regulates the clearance of waste materials generated in nuclear facilities or, in other cases, with criteria prescribed by the regulatory authority, Consejo de Seguridad Nuclear/ Nuclear Safety Council (CSN).

ARTEMIS observation

The ARTEMIS team noted that principles for radioactive waste management contained in the Royal Decree 102/2014 are consistent with the recommendations of the IAEA safety standards regarding waste minimization, accounting for interdependencies, giving priority to safety, application of a graded approach, assurance of funding for all facility life stages, and decision making based on documented empirical evidence.

Further, the ARTEMIS team noted that the Spanish approach to radioactive waste management considers disposal as final destination of all material declared as radioactive waste, and a period of storage is envisaged for waste destined for deep geological disposal. This approach is also consistent with the recommendations of IAEA safety standards.

Formal approval and issuance of the GRWP was undertaken in July 1999 (5th revision) and again in June 2006 (current 6th revision). Whilst ENRESA has made updates of the GRWP in 2010, 2013, 2014 and again in 2015, the Government has not undertaken any formal update of the GRWP since 2006. This is contrary to the spirit of Article 5 (3) of the Royal Decree 102/2014. The ARTEMIS team was further informed that the European Commission has expressed concern that the 2006 revision of the GRWP does not fully meet the requirements of a National programme, as per the Council Directive 2011/70/EURATOMEURATOM of 19 July 2011 establishing a *Community Framework for the Responsible and Safe Management of Spent Fuel and Radioactive Waste* ("*Waste Directive*").

The ARTEMIS team noted from discussion with the Spanish counterparts that a revision of the GRWP is planned, including a process of enhanced public consultation, however, this revision will only be approved following the establishment by the Government of the Integrated National Energy and Climate Plan (2021-2030) which is currently under preparation.

The lack of approval of the updated version of the GRWP by the Government and delays in implementing key elements of the plan, as further analysed in this report, led the ARTEMIS team to question the sustainability of the current strategy for radioactive waste management.

Due to the significance of the general radioactive waste plan, the joint team's recommendation in this regard has been duplicated in both the IRRS and ARTEMIS components of the joint report (recommendations R2 in IRRS and RA1 in ARTEMIS, respectively). Other relevant recommendations are found throughout the joint report and the reader is encouraged to take all these recommendations of report into consideration.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The General Radioactive Waste Plan (GRWP) has not been revised since 2006. ENRESA has provided updates in 2010, 2014 and 2015 however these updated versions have not undergone formal approval by the government. Consequently, there is no formal basis for the current decision making in terms of the long-term management of radioactive waste, raising concerns regarding the sustainability of the current strategy for radioactive waste management.*	
(1)	**BASIS: GSR Part 5 Requirement 2 National policy and strategy on radioactive waste management states that** *"To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles and with international instruments, conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste."*
RA1	**Recommendation: The Government should take immediate steps toward making decisions regarding updates to the GRWP such that the plan can inform decision making to ensure the continued safe and sustainable management, including interim storage and disposal, of radioactive waste in Spain.**

1.2. LEGAL, REGULATORY AND ORGANIZATIONAL FRAMEWORK (PARTLY REFERRING TO IRRS)

Spanish position

The primary legislative instruments defining the legal and regulatory framework are:

(a) Nuclear Energy Act, Law 25/1964;
(b) Law creating the Nuclear Safety Council, Law 15/1980, amended by the Law 33/2007;
(c) 6th Additional Provision of Law 54/1997, on the fund for the management activities under the General Radioactive Waste Plan;
(d) Regulation on Nuclear and Radioactive Facilities, Royal Decree 1836/1999;
(e) Royal Decree 102/2014.

The Ministry for the Ecological Transition (MITECO) is responsible for granting, modifying, suspending or withdrawing authorizations for nuclear and radioactive facilities (except Categories 2 and 3 radioactive facilities, in those Autonomous Communities where such competence is transferred to their Autonomous Governments) after the mandatory report from the CSN. The Autonomous Communities to which these transfers have been made are: the Basque Country, the Balearic Islands, Murcia, Extremadura, Asturias, Madrid, Galicia, Cantabria, Catalonia, the Canary Islands, Ceuta, Navarra, Valencia, Castilla y León, La Rioja and Aragón.

The CSN is the sole competent body in Spain regarding nuclear safety and radiation protection. It is responsible for the nuclear safety assessment of existing and new facilities. The CSN reports are mandatory,

if negative, and, if favourable, the limits and conditions on nuclear safety and radiation protection set in the report, must be included in MITECO authorizations.

ENRESA is responsible for the management of radioactive waste and spent nuclear fuel and the decommissioning and dismantling or closure of nuclear facilities.

ARTEMIS observation

Spain has an established legal and regulatory framework for national nuclear and radiation activities. The overall governmental responsibilities for radioactive waste management and the regulatory framework were reviewed under the auspices of the IRRS component of the combined IRRS-ARTEMIS review mission and consequently not evaluated in detail under the ARTEMIS component. The ARTEMIS peer review of the legal regulatory and organizational framework was restricted to aspects of the legal and regulatory framework in relation to the implementation of the GRWP and is included in the subsequent chapters of this report.

2. NATIONAL STRATEGY FOR RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT

Spanish position

In Spain, radioactive waste is defined as being any material or product for which no further use is foreseen and that contains or is contaminated by radionuclides in concentrations or levels of activity higher than those established by the MITECO, following a report by the CSN.

Radioactive waste is classified (see Chapter 3 for definitions) as:

(a) Very low-level waste (VLLW);
(b) Low and intermediate level waste (LILW);
(c) Special waste (SW) or
(d) High level waste (HLW).

Since 1984, the management of radioactive waste in Spain has been the responsibility of ENRESA, whose activities and financing system are currently governed by Royal Decree 102/2014 and the 6th additional provision of Law 54/1997, respectively.

In accordance with the Advanced Reference Material (ARM), radioactive waste in Spain is generated at a number of nuclear and radioactive facilities distributed throughout the country as illustrated in Figure 1 and Figure 2, in accordance with the classification under Article 2 of Law 25/1964 on nuclear energy. Radioactive wastes may also occasionally be generated in other areas, as a result of specific activities, as well as in occasional incidents (e.g. melting of radioactive sources with scrap metal plant).

At present, the Spanish nuclear programme comprises 5 operational nuclear power plant sites (7 units), spent nuclear fuel storages at six sites– wet in all operational units and in Santa María de Garoña (in administrative shutdown situation since 2013) and dry type in José Cabrera, Trillo, Ascó, Almaraz and Santa María de Garoña, a number of radioactive waste management facilities, including a solid radioactive waste disposal facility (El Cabril) in Sierra Albarrana, in the province of Córdoba, as well as a nuclear fuel fabrication factory in Juzbado (Salamanca). CIEMAT (Research Centre for Energy, Environment and Technology) is in process of dismantling some of its obsolete nuclear research facilities in Madrid.

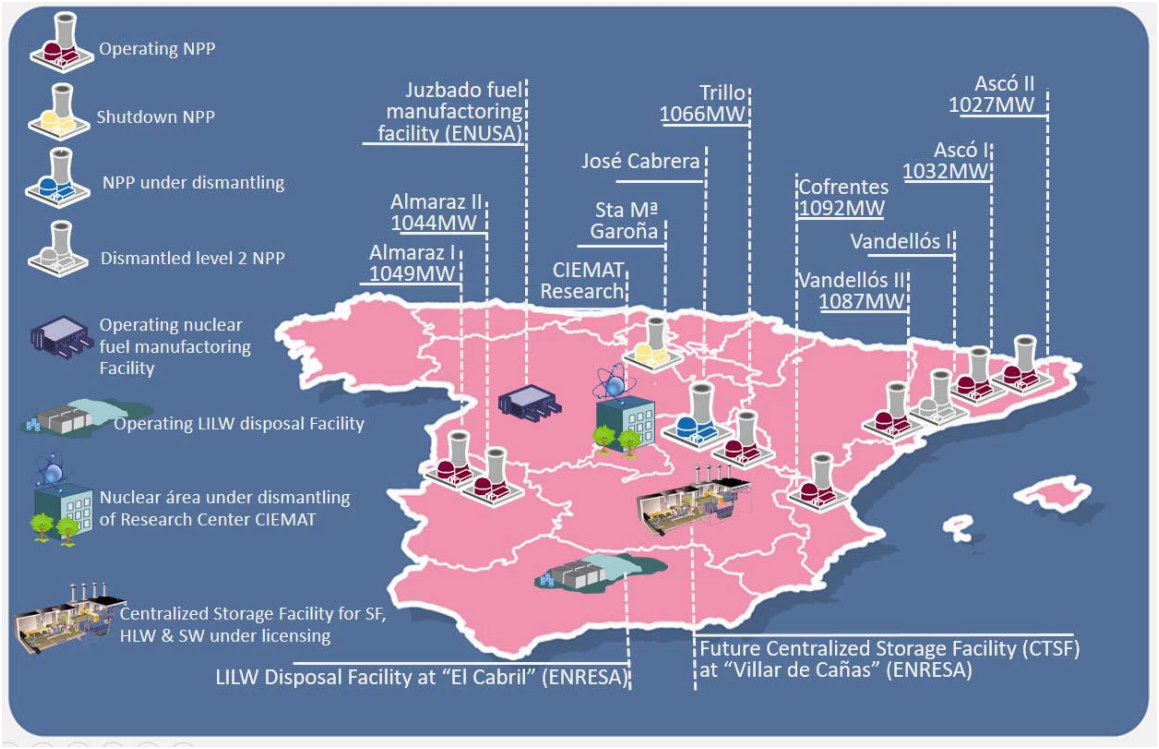


Figure 1: Nuclear facilities in Spain.

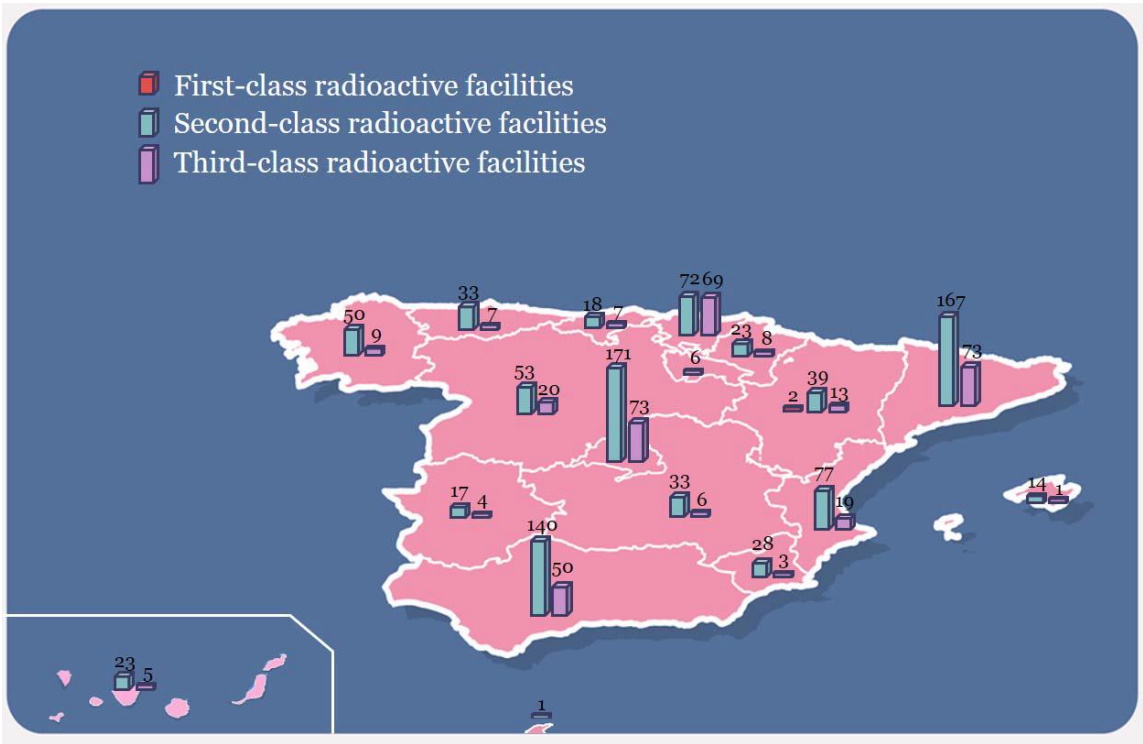


Figure 2: Radioactive facilities in Spain.

Currently Spain has an established near surface facility for the disposal of low and intermediate level and very low-level radioactive waste (the El Cabril Disposal Facility). The management strategy for spent fuel is based on a combination of wet and dry storage at each nuclear power plant site. In addition, a centralized dry storage facility (CSF) for spent fuel and high-level radioactive waste as well as special waste is in process of authorization. Further Spain plans to establish a Deep Geological Disposal facility by the year 2068.

ARTEMIS observation

The Spanish strategy for radioactive waste management includes the following technical solutions:

(a) Clearance of material complying with prescribed criteria;
(b) Near Surface disposal for low and intermediate level waste as well as very low-level radioactive waste at the El Cabril Disposal Facility;
(c) Combination of on-site wet and dry storage facilities for spent nuclear fuel at nuclear power plant sites;
(d) Deep geological disposal of spent fuel and all radioactive waste not suitable for disposal at the El Cabril near surface facility, following an initial period of centralized storage (at the CSF).

The ARTEMIS team considers that the strategy developed in the 6th revision of the GRWP is adequate and includes pragmatic solutions to ensure the safe management of radioactive waste. This strategy is underpinned by the disposal of low and intermediate waste in a near surface facility, the establishment of required individual storage facilities (ISFs) and a proposed CSF, allowing flexibility in terms of capacity and contingency response, to for example possible changes in energy policy or incident situations at ISFs, and a Deep Geological Disposal facility to be realized in the longer-term.

In addition, the ARTEMIS team noted that Spain recognizes the GRWP strategy needs to be supported by environmental assessments and multiple engagements with stakeholders including the public.

Disposal of low and intermediate level radioactive waste (LILW) at the El Cabril Disposal Facility has been in operation since 1992. It was confirmed to the ARTEMIS team that the preliminary treatment and conditioning of LILW at nuclear installations is the responsibility of the nuclear facility operator, who is required to generate waste packages satisfying the acceptance criteria defined by ENRESA for subsequent conditioning and disposal at El Cabril. These are set out in the technical and administrative specifications signed between ENRESA and the waste producers, as it is stated in article 11 of Royal Decree 102/2014. ENRESA has implemented a system of inspections, production controls and verification tests to ensure that packages received at El Cabril meet the established waste acceptance criteria. The waste produced in radioactive facilities is conditioned and treated by ENRESA.

In conformance with IAEA safety standards the safety case for El Cabril is used to support and justify proposed design modifications, waste acceptance criteria and the safe disposal of specific waste on a case by case basis. Further, the ARTEMIS team was informed of waste minimization initiatives that had been implemented.

The ARTEMIS team was informed that two periodic safety reviews of the El Cabril disposal facility had been conducted and presented to CSN at a frequency of approximately 10 years. During these periodic safety reviews, the safety case for the facility was updated taking account of international trends, better integration of the engineering barrier specifications and enhancement of assessment tools and models associated with the facility.

The ARTEMIS team recognises that the operations of the El Cabril facility is in conformance with recommendations of the IAEA safety standards and there have been no significant safety concerns.

At present, 21 of the approved 28 vaults for LILW have been filled as of August 2018, representing 76% of the approved LILW disposal capacity. The need for additional disposal capacity was identified based on the estimates of the current inventory. Consequently, the current licence for the facility will require to be amended to increase the quantities of waste that can be disposed in the facility. The ARTEMIS team was informed that ENRESA has initiated the preparatory tasks for the licence update. Considering that El Cabril facility is central to the management of all LILW in Spain, the extension of the capacity, in due time, is a major objective that must be achieved. It should therefore be included in the revision of the GRWP.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Current available disposal capacity for LILW of the El Cabril facility is limited. The facility is currently 76% full. Consequently, an extension of the current disposal capacity will be required in the near term.*	
(1)	**BASIS: GSR Part 1 Requirement 24: Demonstration of safety for the authorization of facilities and activities states that** *"The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity."*
(2)	**GSR Part 1 paragraph 4.37 states that "***Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure, and shall make provision for the timely submission of applications for the renewal or amendment of the authorization."*
SA1	**Suggestion: ENRESA should consider completing the licence extension application in a timely manner to ensure the continued availability of required disposal capacity. This objective should be included in the update to the GRWP.**

Since 2008 separate disposal of very low-level waste (VLLW) has been conducted at the El Cabril facility. A total of 130000 m^3 of disposal capacity, comprising 4 vaults, has been authorized for disposal of VLLW. ENRESA confirmed to the ARTEMIS team that the available disposal capacity for very low-level radioactive waste is sufficient to address all identified needs.

Spain has previously sent for reprocessing abroad all the spent nuclear fuel from Vandellós I nuclear power plant and some of the spent fuel from José Cabrera and Santa María de Garoña nuclear power plants. This practice was stopped in 1982, except for the spent fuel from Vandellós I NPP, and since 1983 the spent nuclear fuel management policy in Spain follows the open cycle with no planned reprocessing. The spent nuclear fuel is stored at the site of the nuclear power plants in a combination of wet storage (spent fuel pools) or dry storage (individual storage facility – ISF).

The ARTEMIS team was informed that a small quantity of high-level waste and special waste related to the reprocessing of the Vandellós I nuclear power plant will be returned to Spain following availability of the proposed Centralized Storage Facility (CSF). No high-level waste resulting from the reprocessing of

the spent nuclear fuel emanating from José Cabrera and Santa María de Garoña nuclear power plants will be returned to Spain.

As part of its overall waste management strategy, Spain plans to establish a centralized storage facility (CSF) for all spent fuel, special waste and high-level waste including the waste returned after reprocessing. The ARTEMIS team noted that as per the 6th revision of the GRWP the CSF was supposed to be established in 2011 and was considered a vital component of the overall waste management strategy for higher activity waste (spent fuel, special waste, waste from reprocessing abroad and high activity sources). The delay in the establishment of the CSF has implications regarding:

(a) Prompt decommissioning of individual reactor sites since the fuel may still be stored in the pools, in cases where onsite dry storage capacity is not sufficient;
(b) Free release of reactor site at the end of decommissioning, since even if all fuel is removed from the fuel pools it will still be onsite in dry storage;
(c) Availability of facilities and equipment to be able to ensure that the waste can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management in compliance with the IAEA safety standards;
(d) A greater number of Dual-Purpose Casks (DPCs) being deployed at reactor sites, thus reducing the potential for them to be re-used.

In July 2018, MITECO requested the CSN to suspend the current review of the licence application for construction of the proposed CSF for higher level radioactive waste and spent nuclear fuel.

The ARTEMIS team was not provided with evidence that there was any evaluation and/or consideration of the immediate and longer-term safety implications of the decision to temporarily halt the review of the CSF license application. Furthermore, no evidence of stakeholder (including CSN and ENRESA) consultation on this matter was presented to the ARTEMIS team.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no evidence that the decision to delay the review of the CSF licence application included a consideration of appropriate technical and safety factors. The current national plan indicates that the CSF would provide a significant contribution to safety by facilitating the safe management of spent fuel, special waste, other high-level waste at an away from reactor site and permits the completion of all dismantling operations at the reactor site.*	
(1)	**BASIS: GSR Part 5 Requirement 6: Interdependences states that** *"Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option, shall be appropriately taken into account."*
(2)	**GSR Part 5 paragraph 3.21. states that** *"Owing to the interdependences among the various steps in the predisposal management of radioactive waste, all activities from the generation of radioactive waste up to its disposal, including its processing, are to be seen as parts of a larger entity, and the management elements of each step have to be selected so as to be compatible with those of the other steps. This has to be achieved principally through governmental and regulatory requirements and approaches. It is particularly important to consider the established acceptance criteria for disposal of the waste or the criteria that are anticipated for the most probable disposal option."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
RA2	**Recommendation: The Government should ensure, through advice from the competent authority, that any delay in the implementation of the CSF does not negatively impact the safe management of spent fuel and higher-level waste.**

The GRWP foresees the establishment of a Deep Geological Disposal facility as the final destination for high level waste and spent fuel and a commitment to establish the DGD by 2068 has been expressed by the Spanish Authorities in various international forums.

The ARTEMIS team noted that the current plans are only at a conceptual level (only tentative milestones have been proposed). An implementation plan to achieve the 2068 timeframe for establishment of the DGD has not been established and approved at a political level.

The ARTEMIS team, recognizing that the establishment of an operational DGD is an iterative and lengthy process that requires careful and detailed planning, considers that it is important to initiate the step by step development of the DGD as early as possible and to establish measurable performance indicators to evaluate progress.

The ARTEMIS team identified that the current generic authorization framework and regulations do not adequately address the specific legal and regulatory process for establishment of the DGD. Whilst the respective roles of regulator and operator are defined, the impact of the long-time frames and step by step iterative process, requiring multiple stakeholder engagement and regular reaffirmation of political support, is not explicitly covered.

In addition, the ARTEMIS team noted that whilst ENRESA has developed some of the preliminary documents required by the GRWP as early as 2013, these documents have not yet been acted upon to take the process further. ENRESA informed the ARTEMIS team that they are currently waiting for governmental approval to proceed further. This creates uncertainty and poses a risk to the overall delivery of the project as planned and the ability to adhere to the defined deadlines for key milestones. Consequently, the ARTEMIS team recommends specific activities be taken, in parallel by the primary actors (Government, CSN, and ENRESA) to avoid delays and restart of the momentum to develop the Deep Geological Disposal facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is currently a lack of progress in establishing the Deep Geological Disposal facility. This is further hampered by the fact that the existing generic authorization framework and regulations needs to be complemented by regulations and an implementation plan to specifically address the establishment of the Deep Geological Repository (DGD) programme. This creates uncertainty and decreases the likelihood that the project will be able to meet the key milestones and deadlines.*	
(1)	**BASIS: SF-1 Principle 7 Para 3.29 states that "***Radioactive waste must be managed in such a way as to avoid imposing an undue burden on future generations; that is, the generations that produce the waste have to seek and apply safe, practicable and environmentally acceptable solutions for its long-term management. The generation of*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	radioactive waste must be kept to the minimum practicable level by means of appropriate design measures and procedures, such as the recycling and reuse of material."
(2)	**BASIS: SSR-5 Requirement 1 states that** *"The government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need for disposal facilities of different types; specification of the steps in development and licensing of facilities of different types; and clear allocation of responsibilities, securing of financial and other resources, and provision of independent regulatory functions relating to a planned disposal facility."*
(3)	**BASIS: GSR Part 1 Requirement 21 states that** *"The regulatory body shall establish formal and informal mechanisms of communication with authorised parties on all safety related issues, conducting a professional and constructive liaison."*
(4)	**BASIS: SSR-5 Requirement 2 states that** *"The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met."*
RA3a	**Recommendation: The Government should complement the existing legal regulatory framework by developing regulation and an implementation plan for establishing the Deep Geological Disposal facility. This plan should clarify the roles and responsibilities and engagement of the appropriate stakeholders, at each stage of implementation.**
RA3b	**Recommendation: Further, CSN and other competent authorities should develop a plan for regulatory engagement, licensing submissions and regulatory hold points in consultation with ENRESA and other appropriate stakeholders.**
RA3c	**Recommendation: In addition, ENRESA should proactively complete establishment of the technical basis of the geological disposal programme, particularly the site selection process, and define the major milestones with proposed deadlines.**

3. INVENTORY OF SPENT FUEL AND RADIOACTIVE WASTE

Spanish position

In Spain a description of what constitutes radioactive waste is specified in the Nuclear Energy Act (Law 25/1964). The classification of waste is facility specific and is based on a combination of radioactive, chemical and physical properties described in facility specific acceptance criteria.

Radioactive waste is classified as:

Low and Intermediate Level and short-lived waste (LILW): Waste mainly consisting of β and γ emitting radionuclides with a half-life below 30 years and a content of longer-lived radionuclides at very low concentrations. The category includes all wastes which meet the acceptance criteria for El Cabril and also includes the sub-category very low-level waste (VLLW).

Special Waste (SW): Waste that cannot be managed at the El Cabril Disposal Facility due to its high levels of radiation. The category includes materials that have been activated in reactor, wastes from reprocessing activities and neutron sources.

High Level Waste (HLW): Waste that contains significant concentration of α, β and γ emitting radionuclides and is heat generating. The category includes spent fuel declared as a waste and vitrified waste from reprocessing activities.

Prior to November 2017, the unconditional and conditional clearance of solid waste was authorized on a case by case basis by MITECO. With the introduction of Order ETU/1185/2017, CSN is now responsible for the approval of plans for the unconditional clearance of solid waste from nuclear facilities. Gaseous and liquid discharges are still subject to case specific authorizations.

Order ETU/1185/2017 adopts the basic standards outlined in EU Directive 2013/59 EURATOM[2].

ENRESA has the responsibility for compiling the national radioactive waste inventory since its formation in 1984. The first inventory was produced in 1985 and was published in the GRWP in 1987.

The Royal Decree 102/2014, which takes on board the requirements listed in the *Waste Directive*, has resulted in a number of revisions in the scope and methodology used for updating the inventory. The new requirements have resulted in:

- the creation of a new coordination group of experts in VLLW/LILW, SF/SW, decommissioning, safety & licensing, planning and project control;
- the update of the current inventory and future estimates every three years;
- the establishment of a reference case scenario for the disposal of radioactive waste; and
- scenario analysis.

The compiling of the inventory every three years involves waste generators providing actuals (these are recorded as conditioned waste volume) and a projection of future arising for the next 5 years. Future waste projections are generated by ENRESA using the data provided by the waste generators and information provided in individual facility waste and spent fuel plans (regulatory requirement).

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[2] The Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

ENRESA has introduced two databases for recording the detailed information. Waste generators input the information directly into these systems. VLLW and LILW information is recorded in a database termed SGR and SF/HLW/SW in a separate system termed GECYRE (see Figure 3).

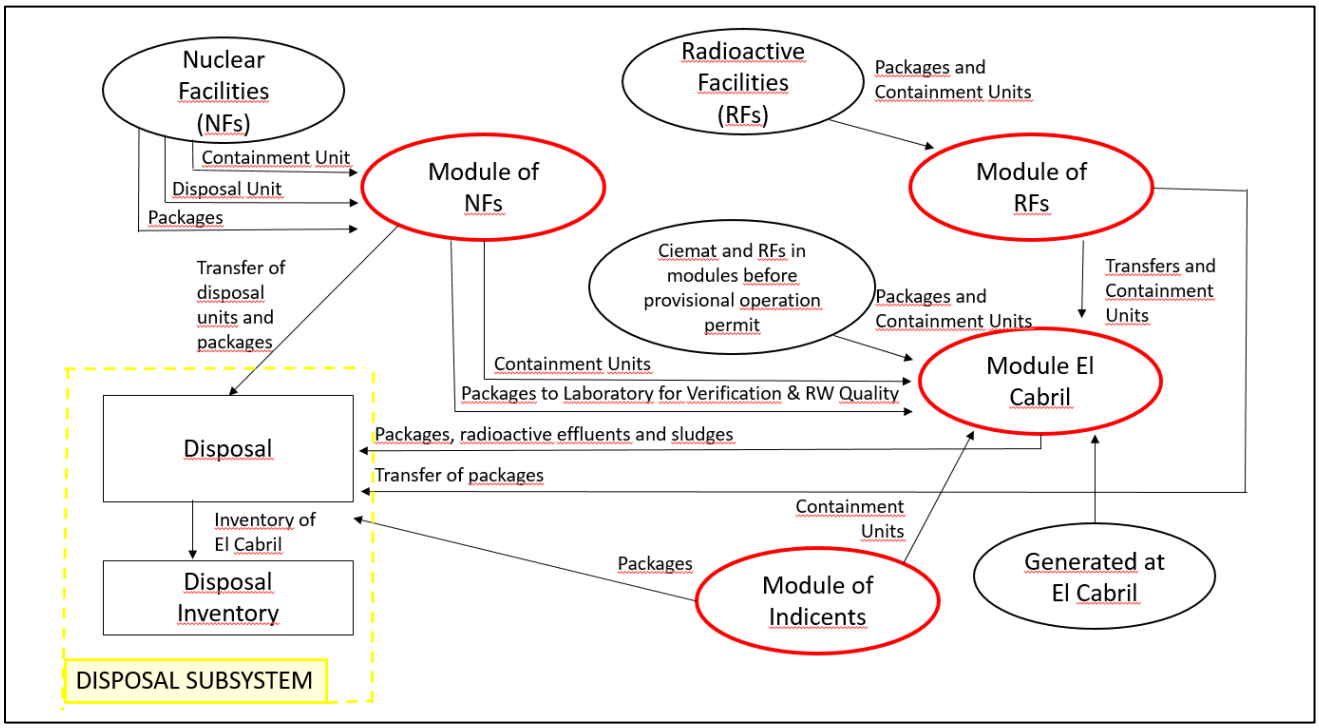

Figure 3: Modules for compiling the radioactive waste inventory

The inventory is reported in the public domain through the GRWP; the latest issue of the plan version 6 was approved in 2006. In addition, a summary of the inventory is routinely reported as part of the requirements under the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (The Joint Convention).

The origins of the waste already generated, and of those that might be potentially generated in the future, are as follows:

(a) Operation and dismantling of the Spanish Nuclear Power Plants (NPP's) José Cabrera, Santa María de Garoña, Vandellós I and II, Ascó I and II, Almaraz I and II, Cofrentes and Trillo;
(b) Operation and dismantling of the Juzbado nuclear fuel manufacturing facility (Salamanca);
(c) Waste generated at the Centre for Energy-Related, Environmental and Technological Research (Ciemat);
(d) Operation and dismantling of the future Centralized Storage Facility (CSF));
(e) Operation and closure of the LILW disposal facility at "El Cabril";
(f) Past reprocessing activities abroad of some spent fuel from José Cabrera, Santa María de Garoña and Vandellós I NPPs;
(g) Application of isotopes in medicine, industry, agriculture and research;
(h) Occasional incidents in non-regulated facilities or activities;
(i) The already dismantled old research reactors and facilities (Coral, Argos, Arbi).

The amounts and the distribution of the different radioactive waste are given in Figure 4.

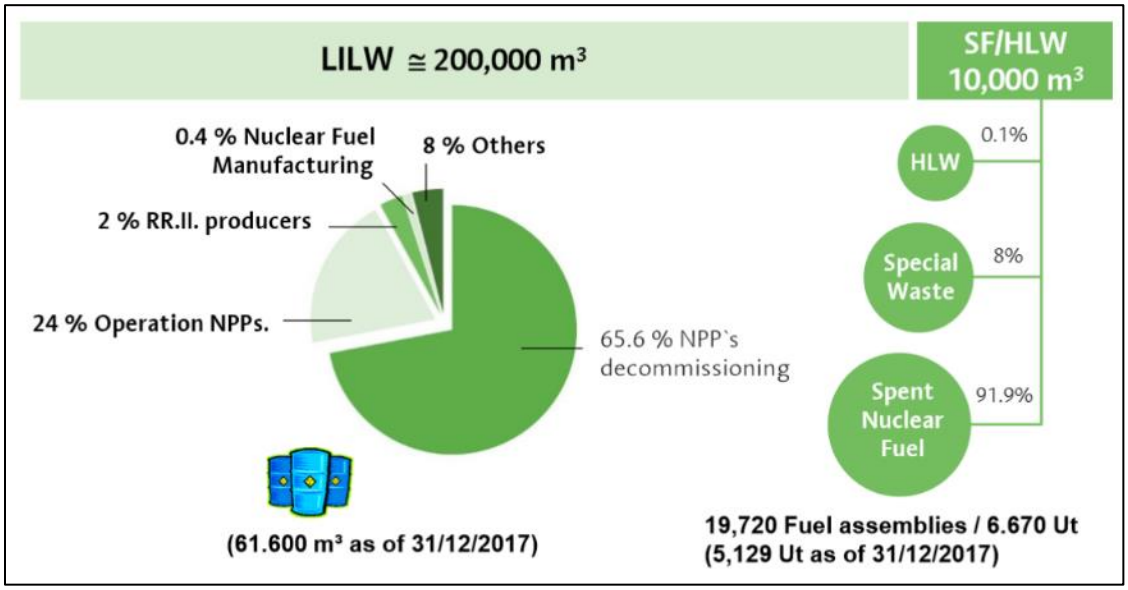

Figure 4: Distribution of radioactive waste by class.

ARTEMIS observation

The process of compiling the radioactive waste inventory is well established and has been subject to continuous improvement.

The ARTEMIS team recognizes that the organization responsible for developing the radioactive waste inventory is probably best placed for analysing the predictions provided by the waste generating organizations.

In updating the radioactive waste inventory, the ARTEMIS team observed that additional utility would be gained by comparing recent and previously published inventories to identify and understand the changes. In this manner, any improvements in areas such as waste reductions, changes in conditioning methodologies, or assumptions in reactor life extensions would become more visible.

The radioactive waste inventory is published and made available to the public through the GRWP (2006) or Joint Convention reports (from 2001). As a means of improving the transparency of this information to the public, the ARTEMIS team considered it noteworthy that ENRESA plans to make the next publication of the radioactive waste inventory available as a separate document on their website.

4. CONCEPTS, PLANS AND TECHNICAL SOLUTIONS FOR SPENT FUEL AND RADIOACTIVE WASTE MANAGEMENT

Spanish position

The El Cabril Disposal Facility (see Figure 5) is a near surface disposal facility with engineered barriers. It accommodates all LILW/VLLW and is based on concrete barriers and concrete disposal units. Conditioned packages of LILW are placed in reinforced concrete containers, or disposal units, which are put in the disposal vaults. It further hosts a disposal facility for VLLW. It has multiple technological capabilities, such as treatment and conditioning facilities for the processing of waste from radioactive facilities and waste removed from non-regulated installations. Further treatment equipment includes a super-compactor and an incinerator for mainly organic waste.

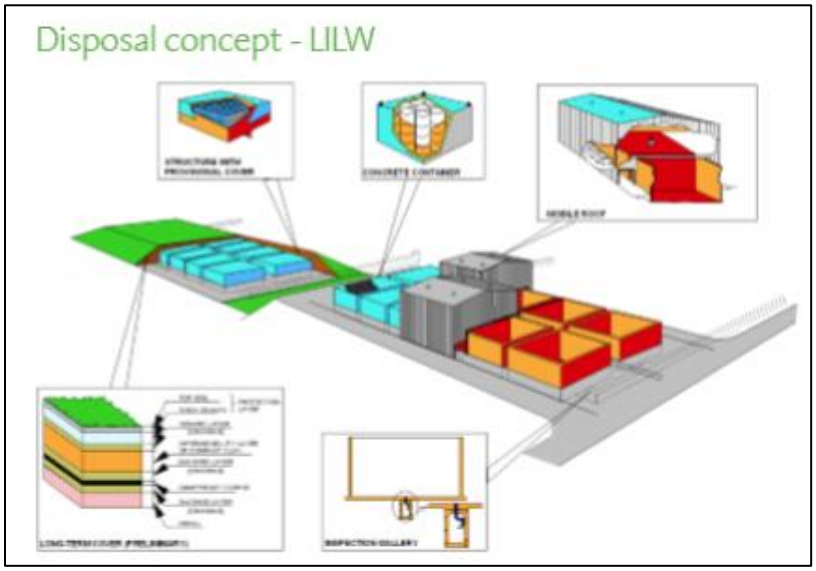

Figure 5: El Cabril disposal concept.

Since 1989 Spain has planned to create a centralized storage facility (CSF) for managing spent fuel, vitrified and special waste while a Deep Geological Disposal facility is developed. The CSF is considered as the optimum solution for Spain as this facilitates decommissioning of reactor sites, and the reduction in the number of operating sites leads to benefits in terms of safety, security and economics.

The conceptual design for the CSF (see Figure 6) has been influenced by the need to store a variety of waste (spent fuel, vitrified and other ILW). The main reference for the facility is the Habog facility in the Netherlands but features of other storage and maintenance facilities have been incorporated into the design; after engaging with designers and operators of other operating facilities. The base technology is a modular vault dry storage (MVDS) integrated with facilities for buffer storing casks, hot cells for packaging fuel into canisters, cask maintenance and hot laboratories for research.

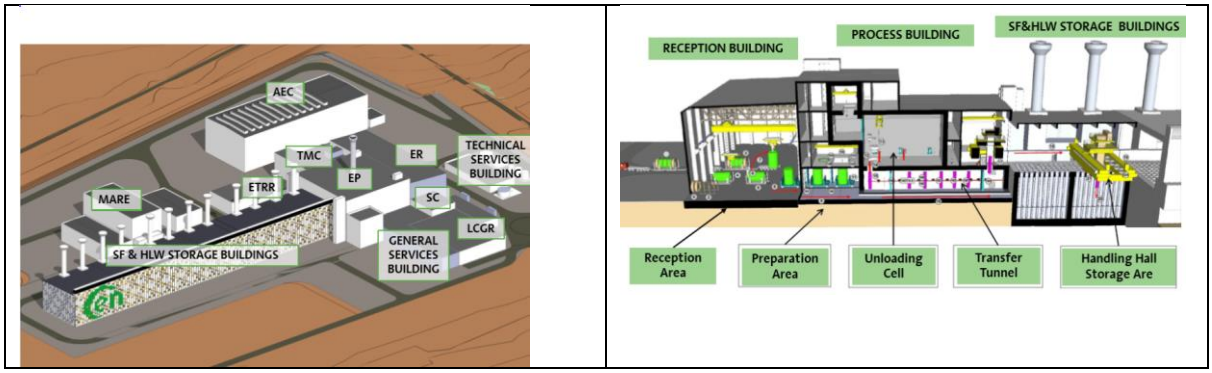

Figure 6: Centralized storage facility (CSF) and cross section of the main process building.

On receipt into the facility, spent fuel is transferred into sealed storage canisters and double stacked in storage tubes cooled by natural convection.

At this stage, there is no detailed plan associated with the transfer of spent fuel from NPPs and ISFs to the CSF. Priority, however, will be given to the return of reprocessing waste from France followed by transfer of spent fuel from José Cabrera ISF (see Figure 7). The overall objective of the transfer plan would be to avoid the generation of new waste through the re-use of dual-purpose casks (DPCs). The situation, however, will be dictated by individual NPP/ISF needs.

The published timeline for build and operation of the CSF is no longer valid. The temporary suspension of licensing activities further delays establishment of the CSF project. Initially seven years to construct and commission the facility was envisaged. This timeline is still considered achievable; as most of the detailed design for the facility has been completed.

Due to the delays in implementing the CSF, contingencies have had to be deployed over the years. In the first instance the re-racking of pools followed by providing individual storage facilities (ISFs) at each reactor site was undertaken. The deployed technology is mainly dual-purpose casks and concrete containers.

Figure 7: Individual Storage Facilities (ISFs) at Trillo, José Cabrera and Ascó NPPs.

Concerning the DGD, a site screening programme between 1985-1996 confirmed that potential locations for a deep geological disposal facility exist in Spain. In the same period safety assessments have been conducted for several non-site-specific conceptual designs. In 2013 a report has been submitted to the government describing basic generic projects for disposal in clay formations and in granitic formations. A tentative schedule for the DGD has been produced. Seven phases have been proposed, including site selection and public participation, detailed site characterisation and validation between 2038-2050 and

DGD licensing and construction between 2050 and 2063. The development of the DGD is supported by certain RD&D activities as described in the 5-yearly RD&D plans produced by ENRESA. The current RD&D plan is covering the period 2014-2018. These activities cover spent fuel characterisation, disposal facility concepts in clay formations and granitic formations in foreign underground research laboratories (Switzerland, Sweden), performance assessment, etc. To complete this RD&D programme ENRESA is relying strongly on international collaboration while developing several competence centres in Spain. During the first decade of this century there was a strong focus of ENRESA on the CSF and a substantial reduction of the RD&D activities supporting the development of the DGD.

ARTEMIS observation

The ARTEMIS team observations regarding the El Cabril facility are included in Chapter 2.

The design basis for the individual storage facilities (ISFs) relies on fuel handling facilities associated with the reactor site being available in the event of any re-work on the stored packages being required.

Central Storage Facility (CSF) - The ARTEMIS team recognises the many benefits of establishing the CSF, especially in relation to delivering the national strategy and removing spent fuel from reactor sites.

The overall design of the CSF, informed through engaging with the designers and operators of existing facilities and adopting best in class, has been formulated with multiple safety features and technical/operational capabilities to provide lifetime flexibility. Safety features include passivity, multiple barriers, subcriticality, the ability to readily retrieve and re-work stored packages, condition monitoring and inspection. Capabilities include the provision of a buffer store to decouple processing operations from processing material for storage, canister loading and sealing, a cask maintenance area so casks can be refurbished to enable re-use, and the concept of coupling research hot laboratories with the MVDS also provides the potential to collect additional data on the spent fuel/stored waste.

Two barriers are claimed in the design, namely the canister and the storage tube. In the unlikely event that more than one barrier was to fail then there are safety margins in the design as no credit is claimed for either the fuel clad or overpack (in the case of damaged fuel). Canister capacities are based on thermal modelling of the facility and not final disposal requirements. This aside, the current packing densities are not too dissimilar to those being used in disposal facility designs abroad. If the canisters are to be used for final disposal, then this will need to be taken in account in the DGD selection/scope to avoid package re-work and additional dose to operators.

The potential for unconditioned damaged fuel to be received into the CSF is considered very low as the conditions for acceptance require that any damaged fuel is conditioned prior to transport. The possibility cannot be ruled out and ENRESA have been asked by CSN to respond to this issue. Moreover, there are available two hot cells where damaged fuel could be managed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The overall design of the CSF has been formulated with multiple safety features and capabilities to provide lifetime flexibility; for example, the receipt and processing of casks and waste packages are decoupled. The design has been informed through engaging with the designers and operators of existing facilities and adopting best in class for each element of the design.*	
(1)	**BASIS: GSR Part 5 Requirement 17, para. 5.14 states that** *"The need for operational maintenance, testing, examination and inspection has to be addressed for the conceptual design stage onwards."*
GPA1	**Good practice: The process of incorporating the best in class in the design of the CSF together with multiple capabilities for the management for spent fuel is considered as good practice.**

Deep Geological Disposal facility (DGD) - Currently, apart from RD&D activities, no progress is made in the deep geological disposal programme. After a phase of site screening in the nineties, the programme for the site selected has practically stalled in the first decade of this century. According to MITECO, up to now, the CSF has been the priority and the planning for the site selection of the DGD is in the very early stages. The ARTEMIS team observed that no official response has been provided to the submission of several reports (including basic generic concepts, feasibility of new technologies, experiences on decision making) that have been submitted by ENRESA in 2013, as already mentioned in chapter 2.

It is observed that the timeline developed by ENRESA for implementing the DGD programme is a first initiative, that requires further development. In addition, the ARTEMIS team noted that the later stages in the timeline are considered overly optimistic and securing this timeline in an implementation plan would enhance predictability and the likelihood for schedule adherence. Such a plan should include the milestones that need to be achieved (next to licencing steps), the actions and activities that are required to meet the milestones and associated time frames. The ARTEMIS team also considers important inclusion of the non-technical aspects into the implementation plan, particularly regarding public participation.

ENRESA is the main holder of technical competence in Spain and in charge of identifying potential sites and implementing a DGD. ENRESA should develop proactively the technical basis supporting each step of the process, which will serve as a basis for the elaboration of the implementation plan.

The ARTEMIS team has made the recommendation in this aspect in chapter 2.

The RD&D programmes are currently primarily driven by bottom-up expert input and the need to maintain competence within a capped budget. A strong coupling between the milestones and activities of the future DGD implementation plan and the RD&D strategy would increase efficiency and strengthen the justification of adequate RD&D funding. A corresponding recommendation is described in chapter 7 of this report.

5. SAFETY CASE AND SAFETY ASSESSMENT OF RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT ACTIVITIES AND FACILITIES

Spanish position

The licensing process for nuclear and radioactive facilities is governed by the Regulation on Nuclear and Radioactive Facilities[3] (RINR). The RINR specifies the content of the safety documentation required by the licensing process of:

- nuclear facilities at all stages (site authorization, construction permit, operating permit, modification to the facility, dismantling permit and declaration of decommissioning). In facilities for the disposal of spent nuclear fuel and radioactive waste dismantling and decommissioning is replaced by dismantling and closure;
- radioactive facilities (the stages at which the safety documentation is required and the content of this safety documentation depending on the category of the facility);
- casks used for the storage of spent fuel.[4]

According to the RINR, safety documentation of nuclear and radioactive facilities has to be updated by the licensee. Periodic Safety Reviews (PSR) are organized every 10 years for the nuclear facilities.

More specifically for radioactive waste and spent fuel management activities and facilities, the following examples are quoted:

Individual storage facilities (ISFs)

In the case of temporary spent fuel storage facilities located at the nuclear power plants, either pools or individual storage facilities (ISFs), the requirements for PSR are included in the authorizations of the NPPs. In the case of spent fuel storage casks, the licensee has to update the safety analysis report (SAR) at least every two years[5].

El Cabril LILW/VLLW Disposal Facility

In order to obtain the exploitation permit for El Cabril, ENRESA submitted in the year 1992 together with other documents, the initial revision of the SAR of this facility, as required by the RINR. Since then, 14 revisions have been done to this document, in order to fulfil the different requirements, set by the CSN, and also to keep updated the SAR. Revision number 6 was related to the approval of the document "Waste acceptance criteria for the Disposal Units"; revision number 9 was done in order to fulfil the requirements related to the design modification for the disposal of VLLW; revision number 13 was related to the authorization of the design modification for the disposal of radioactive sources for isotopes with a half-life between 5 years (Co-60) and 30 years (Cs-137); and the last version of the SAR was edited as a consequence of the beginning of the exploitation of a new vault for the VLLW disposal.

Centralized Storage Facility (CSF)

As part of the submission of the construction licence for the CSF a Preliminary Safety Analysis Report was submitted in January 2014 and revised in August 2015 and May 2018. Additional requests formulated by the CSN are currently being integrated in an updated version which was expected to be submitted to MITECO by the end of 2018. These include supporting documents on spent fuel acceptance criteria, design

[3] Royal Decree 1836/1999, approving the Regulation on Nuclear and Radioactive Facilities, Spanish acronym RINR.
[4] Article 80 of the RINR and CSN Instruction IS-20 of January 28th, 2009.
[5] Article 80 of the RINR and Article 5.5 of the CSN Instruction IS-20 of January 28th, 2009.

basis and parameters, description of the facility, design basis documents, radiological impact assessment in normal operation, accident analysis, pre-operational environmental radiological monitoring programme, human factors engineering programme and structural design reports. Currently the licensing process for the CSF is on hold.

Deep Geological Disposal facility (DGD)

Regarding the safety case development for the DGD, in the past, ENRESA has developed Safety Analysis Reports for generic (non-site specific) conceptual designs for granite (in 2000) and for clay (in 2003). In January 2013 ENRESA submitted a milestone report to MITECO describing basic generic DGD projects for disposal in clay and granitic formations with associated safety assessments. It is expected that the safety case development for the DGD will require a stepwise approach that needs to be captured in a regulatory framework. Such a framework does currently not yet exist. It is expected that an updated safety case will be requested for the following licencing stages: site selection, construction licence, operational licence, license for closure. The safety case structure will be in line with the respective IAEA guideline.

ARTEMIS observation

The regulatory processes for developing and assessing a safety case are well developed. There is a clear allocation of responsibilities. The safe management of RW and SF is supported by appropriate and updated safety documentation at all the (pre-)disposal stages currently available.

From the information given by ENRESA, the ARTEMIS team found an experienced and well-established organization for the safe management of LILW/VLLW from "cradle to grave".

Taking account of interdependencies between management steps, ENRESA developed a waste acceptance system which effectively contributes to the safe management of LILW and VLLW from the generation of the waste up to its disposal in the El Cabril Disposal Facility. ENRESA derived (from the acceptance criteria for disposal units) the acceptance criteria for the waste producers (together with dedicated waste classification), an acceptance methodology and a methodology for waste characterization. This waste acceptance system is subject to upstream quality control at the waste producer site and to downstream quality control (destructive and non-destructive tests) in the El Cabril Disposal Facility premises.

Since 1992, out of 150000 LILW packages disposed of in El Cabril Disposal Facility, only 326 packages are not conforming representing 0.22% of the packages. ENRESA has over 25 years of operational experience and had no major on-site operational incidents.

The ARTEMIS team has not identified any safety issues concerning the ISF according to the ARM and discussions with the counterparts. The ARTEMIS team noted that stress tests have been required to all NPPs and have included spent fuel stored in pools and in dry casks stored in ISF. Stress tests have also been included in the safety case supporting the license application of the CSF. Though no overall assessment could be made by the ARTEMIS team on the safety documentation supporting the licensing of the storage of HLW, Special Waste (SW) and SF in CSF, ENRESA confirmed that there are no safety issues that would require RD&D that need to be resolved to proceed with the licencing of the CSF.

Very few activities take place at present with respect to the development of the safety case for the DGD. The ARTEMIS team underlines that safety assessment will be required for the screening of the sites as part of the site selection process. Furthermore, certain data that will ultimately feed into the safety case for the DGD are being collected and collated today (e.g. characterisation of SF) by producers that will no longer be present when the data are needed. The ARTEMIS team encourages ENRESA to assess whether this data is sufficient to fulfil the requirements for the safety case of the DGD that will be confirmed in the future.

Decisions relating to the use of the vault storage canisters in the CSF as potential disposal canister might affect the safety assessment for the DGD in terms of requirements on canister lifetime, canister loading and thermal impact on the multi-barrier system. The ARTEMIS team encourages ENRESA to analyse these consequences in a preliminary safety case for the disposal facility before confirming the decision to use the vault storage canisters, taking into account the progress in the site selection process at that time.

6. COST ESTIMATES AND FINANCING OF RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT

Spanish position

The 6th additional provision of Law 54/1997 and Royal Decree 102/2014 constitute the main legal basis for cost estimation, funding and financing of safe radioactive waste and spent fuel management, as well as of decommissioning. According to both, the responsibility of covering the cost associated with the management of spent nuclear fuel and radioactive waste in Spain rests with the waste generators, with some exceptions provided by the 6th additional provision of Law 54/1997 on the Electricity Sector which establishes tax rates in order to finance ENRESA waste management services.

The financing of the activities of GRWP is implemented through the Fund *"for the financing of the General Radioactive Waste Plan activities"* that was set up in 1980's only for this purpose. The responsibility for cost estimates and fund management is entrusted to ENRESA. MITECO has the responsibility of strategic management, follow-up and control of ENRESA actions and plans including financial actions. The Monitoring and Control Committee, under MITECO, has the responsibility to monitor the investments of Fund's assets.

The basis of cost estimates and funding is established in the GRWP, which in accordance of Royal Decree *"…shall contain the strategies, actions required and technical solutions to be implemented in Spain in the short, medium and long term, aimed at the responsible and safe management of spent nuclear fuel and radioactive waste, the decommissioning and closure of nuclear facilities and the other activities related to the above, including economic and financial forecasts and the measures and instruments needed to carry them out."*

The Fund covers financing of ENRESA activities, the management of radioactive waste and spent fuel from all facilities and also activities related to decommissioning and dismantling of nuclear facilities. The decommissioning of radioactive facilities is financed directly by licensees.

The basis (reference scenario) for cost estimations included in the GRWP is the following:

- Current nuclear power plant fleet with seven operational NPP units are located in five sites. It is assumed that the operational life-time of each unit is 40 years with future operational performance similar to the current one. New NPP units are not considered.
- Open fuel cycle is assumed with domestic disposal endpoint. Reprocessing is not considered.
- Interim storage of spent fuel in the CSF is assumed before final disposal in a domestic deep geological facility.
- Immediate and complete dismantling strategy of light water nuclear power plants to be commenced three years after their final shutdown, considering a 7-year execution term. In the case of Vandellós I NPP, final decommissioning is expected only after a quiescent phase due to technical reasons, considering a 10-year execution period.
- For small producers (medical, research and industrial facilities without affiliation to the nuclear fuel cycle), a similar waste generation to the current one has been considered until the year of closure of El Cabril facility.

The Fund for financing of GRWP activities is based on a system of taxes and revenues from fund investments. The system of taxes consists of the taxes included in the electricity tariff, taxes charged on NPPs based on electricity production, fee from the nuclear fuel manufacturing facility and fees from radioactive waste facilities.

ARTEMIS observation

The updates of GRWP after 2006 have not been approved by the Government. For this reason, the current GRWP in force does not contain up-to-date information about inventory, time schedules for planned facilities or activities or updated cost estimates. However, ENRESA has updated annually the cost estimates for radioactive and spent fuel management and decommissioning of nuclear facility. ENRESA has proposed estimates that include changes to the GRWP reference scenario. For example, the estimated times for decommissioning of NPPs have been increased from 7 to 10 years. The ARTEMIS team considers that the initial consideration of 7 years for decommissioning was optimistic.

The ARTEMIS team recognizes that a comprehensive funding mechanism and system exist in Spain. By law, the capitalized Fund under ENRESA's management is appropriately segregated, i.e.: it is allowed to be used only for those activities directly linked with the implementation of the GRWP.

Within specific restrictions established in regulation, a certain part of the capital in the Fund can be used for temporal investments, but yields shall always be transferred back to the Fund. These investments are under the control of several bodies independent from ENRESA.

The annual revenues of the Fund originate almost entirely (99.7% in 2017) from tax payments of operational NPPs, while other non-NPP waste producers (Juzbado, institutions) make a nominal contribution. In addition, there is revenue originating from electricity transport tolls in order to cover management costs associated with NPPs shut down before 2010. This funding route can also be used in case of insufficient funding to cover GRWP implementation.

In general, the distribution of financial contribution is in line with the polluter pays principle.

The financing mechanism and system are designed in a manner which enables the sum of discounted annual revenues to cover all discounted expenditures from the Fund at the end of the GRWP planning period.

The regulations require ENRESA to perform an annual cost assessment of GRWP that is submitted to MITECO. This mechanism makes it possible to annually evaluate the overall costs and the adequacy of the accumulation of the Fund. Despite the fact that none of the updates of the GRWP have been formally adopted by the Government since 2006, ENRESA has annually updated the cost calculations, taking into account the necessary changes. This has enabled regular evaluations of Fund revenues and identification of needs for changes. Currently, the Fund is in its accumulation phase i.e.: the annual revenue has been exceeding the annual expenditures since 1980's. Nevertheless, the ARTEMIS mission has identified the following issues that require addressing:

- ENRESA's current calculations predict a shortfall in the level of funding if the tax rate is not increased. The ARTEMIS team noted that the tax rate has not been revised since 2010;
- Costs estimates and, consequently, the derived financial needs of the Fund in the future are subject to uncertainties associated with various factors (e.g.: variations in time schedule, lack of specific cost element for DGD, etc.);
- The funding mechanism does not provide any financial guarantee for the scenario of early shut down (less than 40-year operational life). In the case that the shutdown is due to the will of the licensee, the regulation requires that the licensee makes up the deficit. In the case that the licensee cannot pay the deficit, the tax included in electricity tariff will assume the deficit.

ENRESA is aware of these issues and has already considered introducing some probabilistic approach in order to treat risks and uncertainties in the future. The ARTEMIS team acknowledges this approach and considers in addition that there is a need for routinely reviewing the funding mechanisms in order to ensure the implementation of the radioactive waste and spent fuel management programme.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *According to the regulation, ENRESA performs an annual cost assessment of GRWP which is submitted to MITECO each year. In the past years the tax rates prescribed in the regulation have been below the appropriate values that would cover the costs for the realization of the National Waste Management Programme, according to ENRESA estimations. In addition, the regulation has not been amended since 2010. Consequently, the annual revenues to the Fund are less than ENRESA's detailed cost calculations. Further, robustness of the funding mechanism could be questioned by possible evolutions of the nuclear energy policy.*	
(1)	**BASIS: GSR Part 1 Requirement 10: Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel states that** *"The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel.* *2.33. Appropriate financial provision shall be made for:* *(a) Decommissioning of facilities;* *(b) Management of radioactive waste, including its storage and disposal;* *(c) Management of disused radioactive sources and radiation generators;* *(d) Management of spent fuel."*
(2)	**GSR Part 5 Requirement 1: Legal and regulatory framework states that** *"The government shall provide for an appropriate national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This shall include the clear and unequivocal allocation of responsibilities, the securing of financial and other resources, and the provision of independent regulatory functions. Protection shall also be provided beyond national borders as appropriate and necessary for neighbouring States that may be affected."*
(3)	**SSR-5 Requirement 1: Government responsibilities states that** *"The government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need for disposal facilities of different types; specification of the steps in development and licensing of facilities of different types; and clear allocation of responsibilities, securing of financial and other resources, and provision of independent regulatory functions relating to a planned disposal facility."*
RA4	**Recommendation: The Government should routinely review the funding mechanism, including the need to update tax rates, to ensure adequate and timely financing of NPP decommissioning, Centralized Storage Facility development, Deep Geological Disposal facility programme development and implementation and other radioactive waste and spent fuel management activities.**

7. CAPACITY BUILDING FOR RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT – EXPERTISE, TRAINING AND SKILLS

Spanish position

Human Resources Management

Legal provisions

The provisions of different organizations having responsibilities in safe management of radioactive waste and spent fuel are established in legislation. Especially Law 15/1980 and Royal Decree 1440/2010 provide the provisions that require the establishment and maintenance of competences and skills within the regulatory body. The Law 25/1964 provides the provisions concerning the competences for personnel working in radioactive waste or spent fuel management facilities. The law requires that the organizations responsible shall have all the necessary human and technical resources needed to maintain safety and further on the law requires that the staff of nuclear and radioactive facilities shall meet the eligibility conditions established by relevant regulations. The requirements for expertise, training and qualification for nuclear facilities staff are further elaborated in CSN safety instructions. The role of ENRESA and functions are expanded in the Royal Decree 102/2014. In relation to expertise, training and skills the decree mandates ENRESA to establish "*training plans and research and development plans within the framework of the State Plan for Scientific and Technical Research and Innovation, covering the needs of the General Radioactive Waste Plan and enabling the acquiring, maintenance and continued development of the necessary knowledge and skills."*

Organization and staffing

At the national level the main organizations for the management of radioactive waste and spent fuel are MITECO, ENRESA and CSN. The capacities of CSN are addressed in IRRS part of this report. According to the ARM and the discussions with the Spanish counterparts, the staffing of MITECO and ENRESA are the following:

- MITECO. With a staff of 13 persons, the Deputy Directorate-General for Nuclear Energy of MITECO employs 10 engineers/scientists and 3 administrative employees. It is organized in four areas: one for the front-end of the nuclear fuel cycle and international relations; one for the back-end of the nuclear fuel cycle; one for the nuclear and radioactive facilities; and finally, one covering nuclear safeguards, transports and security.
- ENRESA. According to the ARM and specific presentations, ENRESA has in overall staff of 328 people, of which 185 are employed at the Madrid headquarters of the company, 123 at the El Cabril facility, 6 at the Vandellós I site, 11 on the José Cabrera NPP dismantling site and 3 in the Centre of Villar de Cañas. As regards academic qualifications, 57% of the personnel are graduates, 25% have intermediate level qualifications and 18% have other qualifications. The technical direction of ENRESA is divided in three entities: an Engineering Direction, the Direction of the El Cabril site and an Operational Direction and also includes a Department for Safety and Licensing, a Department for International Cooperation and a Projects Coordination Unit.

ENRESA is bounded by public sector employment requirements which restrict its flexibility in recruiting.

The average age of the ENRESA personnel is at the present time 52 years and follows an increasing tendency. This evolution is a challenge for renewing and maintaining skilled personnel in the coming years. The ENRESA's Direction of Organisation and Human Resources carries out yearly estimates of resources

needs. ENRESA has indicated also that longer time resources needs will be integrated as a new chapter of the GRWP. The aim is to increase awareness of the Government on this issue.

Training

ENRESA's training programmes, in relation to competences in safety management, consist of corporate general training and facility specific training. ENRESA's Training department is responsible for preparing a training plan. For the period of 2016-2017 the training plan defined the following objectives:

- Strategic Objectives: Increase the company knowledge capital; promote the transmission of knowledge between jobs; increase the employee's entailment and alignment with the company goals; and strengthen the organizational safety culture;
- Instrumental Objectives: Acquire and improve the management skills of each group; promote the competence management; establish training follow up; elaborate integrated development projects according to the employee's needs and organizational changes as well as in case of new recruitments; facilitate access to promotion and mobility for man and woman; and encourage and promote a strong safety culture.

The facility specific trainings are focused on developing competencies directly related to work activities in the dedicated facility. For instance, all nuclear fuel cycle facilities are required to develop a training plan for the specific training actions in accordance with the current legislation.

A system of granting licenses and qualifications for the personnel having duties and/or responsibilities in the safe management of nuclear and radioactive facilities is regulated in the Regulation on Nuclear and Radioactive Facilities[6] (RINR). This system is monitored and controlled by the CSN.

At a national level, ENRESA collaborates with several universities for the development of training courses related to radioactive waste management, radiation protection and nuclear engineering.

R&D to support capacity building

The GRWP defines the national policy and strategies for radioactive waste management and outlines the R&D areas to be considered. The content on GRWP is prescribed in Royal Decree 102/2014, which in relation to R&D, states that GRWP shall outline "*the research, development and demonstration activities that are needed in order to implement solutions for the management of the spent nuclear fuel and radioactive waste, as well as for carrying out the decommissioning and closure of nuclear facilities*." As mentioned above, the article 9 of the Royal Decree mandates ENRESA to establish R&D plans for the needs described in the GRWP.

The role of MITECO in R&D has been established in the Royal Decree 864/2018, which states that one of the ministry's tasks is to contribute, in collaboration with the Ministry of Science, Innovation and Universities, to the definition of the policy of research, technological development and demonstration within the energy field. MITECO has also the responsibility to monitor and control the actions and plans of ENRESA. For this purpose, R&D plans developed by ENRESA are submitted to MITECO.

The first ENRESA's R&D plan was introduced for a five-year period (from 1987 to 1991) and since then ENRESA has prepared six five-year R&D plans. Strategic focus on VLLW/LILW management, SNF/HLW interim storage, geological disposal, decommissioning, CSF related technological support, continuous improvement of safety and knowledge management, have been included in the current R&D plan.

According to the ARM, R&D in the 2014-2018 period is also focusing on four technical areas:

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[6] Royal Decree 1836/1999, approving the Regulation on Nuclear and Radioactive Facilities, Spanish acronym RINR.

- Technology and knowledge of the waste;
- Process technology for treatment, conditioning and dismantling;
- Confinement materials and systems;
- Safety assessment and modelling.

The 8th ENRESA's R&D plan is currently being drafted. According to ENRESA, the plan will follow the same strategic lines as 7th R&D plan. In the planning, the following main radioactive waste management milestones and related needs have also been taken into account:

- CSF licensing, construction and operation;
- design, licensing, construction and operation of a technological centre integrated within the CSF; increasing of El Cabril disposal capacity;
- end of decommissioning in Jose Cabrera NPP and start of decommissioning of Garoña NPP.

ENRESA is the main contributor to the radioactive waste and spent fuel related R&D. However as there is a large number of organizations involved in nuclear related research, MITECO initiated in 1991 a Strategic Nuclear R&D Committee for the coordination of Spanish R&D work. In 2007 the committee work evolved to the Spanish R&D Technology Platform of Fission Nuclear Energy (CEIDEN), whose purpose is to bring together all the stakeholders of the nuclear energy sector including MITECO, CSN, the universities and research centres, the operators and the industry associations. The aim of the platform is to identify synergies and points of common interest in research programmes and activities and to coordinate participation in the international R&D programmes.

ARTEMIS observation

ENRESA has developed over the past decades a strong capacity to carry out its roles and responsibilities in many fields of radioactive waste and spent fuel management (projects, operation of the El Cabril facility, maintain and development of its expertise and skills, …). ENRESA has however over the past years encountered difficulties in recruiting new employees and faces the challenge of an ageing workforce. ENRESA is aware of this challenge and has already taken some measures: for instance, by strengthening the documentation of essential know-how accumulated through several RD&D projects. The latter measure is recognized by the Review Team as a good example of knowledge transfer and dissemination within the company. However, to address comprehensively this challenge, the strategy and processes for knowledge transfer should be further developed by ENRESA.

The Royal Decree establishes clearly the expectations for GRWP to outline the R&D areas needed for safe radioactive waste and spent fuel management. The role of ENRESA is also clearly established and through production of several consecutive R&D plans ENRESA has a well-established process for R&D planning. The selected strategic focus areas and main technical R&D areas provide opportunities for ENRESA personnel to develop their competences and also use the outcomes of R&D in waste management activities (e.g. El Cabril, CSF, decommissioning).

Through the series of R&D programmes, ENRESA has established a comprehensive national and international network of research organisations that can also contribute to safety of ENRESA's facilities and activities. ENRESA has also been active and well acknowledged member in international R&D programmes. The ARTEMIS team considers that the CEIDEN platform is a useful mechanism to coordinate R&D work and to disseminate the results.

ENRESA prepares R&D programmes for five-year periods. The financing of R&D programmes over the years 1991-2003 was around 35 to 42 M€. During this period ENRESA had established a comprehensive R&D programme for DGD development. According to ENRESA about 75% of the programme budget was allocated to DGD projects. The funding of the latest R&D programme (2014-2018) had decreased to 12 M€

and the funding of DGD related projects was around 2 M€. The ARTEMIS team considers that the decrease of DGD related R&D activities has been significant and further continuation of such a limited investment could jeopardize maintenance of the competences developed by ENRESA over the past decades.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ENRESA is bounded by public sector employment requirements which restrict its flexibility in recruiting. Further, ENRESA faces the challenge to ensure knowledge continuity due to retirements. The strategy and processes for knowledge transfer should be further developed to address comprehensively this challenge.*	
(1)	**BASIS: GSR Part 2 Requirement 9, para. 4.27 states that** *"The knowledge and the information of the organization shall be managed as a resource."*
SA2	**Suggestion: ENRESA should consider ensuring that the strategy and mechanisms are in place to avoid the loss of knowledge and know-how on radioactive waste and spent fuel management.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ENRESA prepares five-year R&D programmes. The funding of R&D programmes has decreased significantly in recent years and the emphasis has changed from DGD projects to other areas of radioactive waste and spent fuel management. The current investment in deep geological disposal projects allows ENRESA to follow international developments but does not provide sufficient funding for maintaining and improving the competences needed to support the implementation of the Deep Geological Disposal facility programme.*	
(1)	**BASIS: SSR-5 Requirement 3, para. 3.13 states that** *"The operator has to conduct or commission the research and development work necessary to ensure that the planned technical operations can be practically and safely accomplished, and to demonstrate this. The operator likewise has to conduct or commission the research work necessary to investigate, to understand and to support the understanding of the processes on which the safety of the disposal facility depends. The operator also has to carry out all the necessary investigations of sites and of materials and has to assess their suitability and obtain all the data necessary for the purposes of safety assessment."*
RA5	**Recommendation: ENRESA should re-evaluate the adequacy of R&D funding needed to support the step-by-step development of the Deep Geological Disposal programme.**

APPENDIX A: TERMS OF REFERENCE

ARTEMIS Review of the Spanish Policy on Spent Fuel and Radioactive Waste Management

Terms of Reference

1. Introduction

On 9th of June of 2016, the Permanent Mission of Spain to the International Organizations in Vienna (the "Permanent Mission") requested the International Atomic Energy Agency (the "Agency") to organize and carry out, an ARTEMIS Review (the "ARTEMIS Review"), in the framework of the obligations under Article 14.3 of the Council Directive 2011/70/EURATOM of 19 July 2011 *establishing a Community Framework for the Responsible and Safe Management of Spent Fuel and Radioactive Waste* (the "EU Waste Directive"), combined with an Integrated Regulatory Review Service (the "IRRS review"). The dates for the mission are from 14th to 26th October 2018. The present Terms of Reference refers only to the ARTEMIS component of the mission.

2. Objective

The ARTEMIS Review will provide an independent international evaluation of the Spanish Radioactive Waste and Spent Fuel Management Programme, in line with the obligations of the EU Waste Directive.

The ARTEMIS Review organized by the Department of Nuclear Safety and Security and the Department of Nuclear Energy of the IAEA will be performed against the relevant IAEA Safety Standards and proven international practice and experiences with the combined expertise of the international peer review team selected by the IAEA.

The ARTEMIS Review will be implemented with recognition of IRRS review, as both reviews were requested to be organized at the same time, to facilitate the benefits resulting from mutual use and exchange of the materials and results.

According to preliminary discussions, the responsible counterparts for the ARTEMIS Review for Spain are Mr. Javier Díes (coordinator for the IRRS/ARTEMIS combined mission), Mr. José Manuel Redondo and Mr. Álvaro Rodríguez (ARTEMIS liaison officers).

3. Scope

The ARTEMIS Review will assess, as requested by the EU Waste Directive, the national framework, the competent regulatory authority and the national programme for the management of all types of radioactive waste and spent fuel in Spain. In accordance with that, ARTEMIS review service will cover all the topics under the domain "National policy, framework and strategy" as stated in point 6 "Structure of ARTEMIS Review Service" of the guidelines for this type of mission.

As indicated in the letter of the Permanent Mission dated 9th June 2016, both ARTEMIS and IRRS are expected to be organized mutually, therefore the regulatory aspects relevant to ARTEMIS review, i.e. relating to radioactive waste and spent fuel management, are to be covered by the IRRS review and exchanged in the whole course of implementation of both reviews. Regular interactions between the

ARTEMIS team and the IRRS team during the mission will ensure the exchange of information and avoid duplication of the work.

4. Basis for the ARTEMIS Review

The ARTEMIS Review will be carried out, following the guidelines of the ARTEMIS Review service posted in the IAEA Global Nuclear Safety and Security Network webpage (https://gnssn.iaea.org/main/ARTEMIS/Pages/default.aspx) in the version submitted by the IAEA to Spain in January 2017, against the relevant IAEA safety standards and proven international practice and experience with the combined expertise of the international peer review team selected by the IAEA.

5. Advance Reference material

The **Advance Reference Material** will encompass all documentation submitted by Spain according to the scope of the review, the guidelines for the ARTEMIS Review service and the responses to the self-assessment questionnaire.

For the ARTEMIS review mission, the National Counterparts assess, what documents shall be provided to the review team, based on the undertaken self-assessment. The content of Reference Material will be discussed and finalized during the preparatory meeting.

The Advance Reference Material ARTEMIS mission should be submitted at the latest two months before the combined mission (the sooner the better).

All documents for the purpose of the ARTEMIS Review have to be submitted in English.

6. Language

The working language of the ARTEMIS Review will be English.

7. Timeline

The proposed timeline for the ARTEMIS Review is the following:

- Guidelines for ARTEMIS review service: available to Spain as of early 2017
- Self-Assessment questionnaires and bases for the ARTEMIS reviews: available to Spain as of early 2017
- Preparatory Meeting: 25th -26th January 2018 (2 days)
- Receipt of English documents for the purpose of the review: at the latest 2 months before the ARTEMIS Review mission (including self-assessment responses)
- Peer review mission: within the period of 14th to 26th October 2018 - 11 Days (precise dates will be confirmed during the preparatory meeting) with the following sequence (to be confirmed at preparatory meeting):
    - Arrival for Sunday expert team meeting,
    - Monday to Friday: interviews/exchange/discussion with Counterpart(s) on the basis of preliminary analysis and drafting of recommendations and suggestions
    - Saturday-Sunday: drafting of the report
    - Monday: Delivery of draft report/recommendations – fact checking by counterpart(s) and discussions

- Tuesday: discussions – finalization of draft report
- Wednesday: report delivery – closure
- Once the mission team has delivered the draft report the ARTEMIS Deputy Team Leader (François Besnus) and the IAEA Team Coordinator (Gérard Bruno), will stay in the host country for participating in the exit meeting of the combined IRRS-ARTEMIS mission, which is planned to be organized on Friday morning of the second week of the IRRS mission.

8. International peer review team

The team should consist of:

- The Team Leader (TL) of the combined IRRS-ARTEMIS mission (Victor McCree, US-NRC);
- Two sub-teams:
  - For the IRRS mission: a Deputy Team Leader (DTL) (Carl Magnus-Larsson, ARPANSA), an IAEA Team Coordinator (TC) (Jean-René Jubin) and a Deputy Team Coordinator (DTC) (tbd), and ~25 Review Team experts (tbd);
  - For the ARTEMIS mission: a Deputy Team Leader (François Besnus), an IAEA Team Coordinator (Gérard Bruno), an IAEA Deputy Team Coordinator, an IAEA Assistant and ~7 Review Team experts (tbd) from decision making bodies, waste management organizations and technical support organizations, with experience in the safe management of radioactive waste and spent fuel.

The IAEA will formally inform Spain regarding the composition of the proposed review team prior to conducting the ARTEMIS Review.

The designations of both the DTL of the ARTEMIS mission and the Review sub-team experts will be further discussed and eventually agreed upon at the preparatory meeting, planned in January 2018. The DTL of the ARTEMIS mission will act as a reviewer and should therefore be proposed by the IAEA, as the other Review Team experts.

The ARTEMIS review mission will be observed by no more than a total of 2 observers. The inclusion of observers may be proposed by the IAEA for consideration by the host country in advance to the mission.

9. Reporting

The findings of the ARTEMIS Review will be documented in a final report that will contain the proceedings, and the recommendations and suggestions. The report will reflect the collective views of the team members and not necessarily those of their respective organization or of Member States or of the IAEA.

The ARTEMIS report will be combined with the IRRS report to form a single mission report.

Spain is encouraged to make the mission report public. 90 days after the transmission of the final report of the mission, the IAEA will make the report publicly available unless the host country specifically requests that it remains restricted.

According to preliminary discussions, Spain indicated its intention to publish the final mission report of the IRRS/ARTEMIS review.

10. Funding of the ARTEMIS Review

The ARTEMIS Review will be funded by Spain. The costs for the services will be limited to the travel costs and per diem of the peer review team (external experts and IAEA staff members) and external expert fees in line with IAEA Financial Regulations and Rules.

The costs of official publication (if decided) of the final peer review report will also be covered by Spain.

By agreeing to the Terms of Reference it is understood that Spain accepts to cover the full cost of the ARTEMIS review, currently estimated at Euro XXX. Spain is aware that the cost of the review includes 7% programme support costs.

APPENDIX B: MISSION PROGRAMME

Time	Sun, 14 Oct.	Mon, 15 Oct.	Tue, 16 Oct.	Wed, 17 Oct.	Thu, 18 Oct.	Fri, 19 Oct.	Sat, 20 Oct.	Sun, 21 Oct.	Mon, 22 Oct.	Tue, 23 Oct.	Wed, 24 Oct.
9h30 - 13h00		Entrance Meeting at CSN	National Strategy at ENRESA	Concepts, Plans and technical solutions at ENRESA	Cost estimates and financing at ENRESA	**Finalization of Recommendations and Suggestions** at ENRESA	Drafting of the report	Drafting of the report	**Review of the draft report by the Counterparts**	Finalising the draft report	**IRRS-ARTEMIS Closure Meeting** **Delivery of the final draft report**
13h00 - 14h00	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch		Lunch	Lunch	
14h00 - 15h00	IRRS-ARTEMIS Plenary Meeting	National Policy and Framework at ENRESA	Inventory at ENRESA	Safety case and safety assessment at ENRESA	Capacity building at ENRESA	**Presentation and discussions of Recommendations and Suggestions with the Counterparts** at ENRESA	Drafting of the report	Lunch at Los Galayos Restaurant	**Discussions with the Counterparts on the draft report** at ENRESA	Finalising the draft report	Departure of Team Members
15h00 - 16h00	Initial ARTEMIS Team meeting										
16h00 - 17h00								**Draft report to be sent to the Counterparts**			
17h00 - 18h00		Team meeting and drafting of the report	Team meeting and drafting of the report	Team meeting and drafting of the report	Team meeting and drafting of the report	Team meeting and drafting of the report			Team meeting		
18h00 - 19h00		IRRS - ARTEMIS Coordination Meetings	IRRS - ARTEMIS Coordination Meetings	IRRS - ARTEMIS Coordination Meetings	IRRS - ARTEMIS Coordination Meetings					Social Dinner at Casino de Madrid	

APPENDIX C: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICESS

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	**NATIONAL POLICY AND FRAMEWORK FOR RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT**	**RA1**	The Government should take immediate steps towards approval of updates to the GRWP such that the plan can inform decision making to ensure the continued safe and sustainable management, including interim storage and disposal, of radioactive waste in Spain.
2.	**NATIONAL STRATEGY FOR RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT**	**RA2**	The Government should ensure, through advice from the competent authority, that any delay in the implementation of the CSF does not negatively impact the safe management of spent fuel and higher-level waste.
		RA3a	The Government should complement the existing legal regulatory framework by developing regulation and an implementation plan for establishing the Deep Geological Disposal facility. This plan should clarify the roles and responsibilities and engagement of the appropriate stakeholders, at each stage of implementation.
		RA3b	Further, CSN and other competent authorities should develop a plan for regulatory engagement, licensing submissions and regulatory hold points in consultation with ENRESA and other appropriate stakeholders.
		RA3c	In addition, ENRESA should proactively complete establishment of the technical basis of the geological disposal programme, particularly the site selection process, and define the major milestones with proposed deadlines.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		SA1	ENRESA should consider completing the licence extension application in a timely manner to ensure the continued availability of required disposal capacity. This objective should be included in the update to the GRWP.
4.	**CONCEPTS, PLANS AND TECHNICAL SOLUTIONS FOR SPENT FUEL AND RADIOACTIVE WASTE MANAGEMENT**	**GPA1**	The process of incorporating the best in class in the design of the CSF together with multiple capabilities for the management for spent fuel is considered as good practice.
6.	**COST ESTIMATES AND FINANCING OF RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT**	**RA4**	The Government should routinely review the funding mechanism, including the need to update tax rates, to ensure adequate and timely financing of NPP decommissioning, Centralized Storage Facility development, Deep Geological Disposal facility programme development and implementation and other radioactive waste and spent fuel management activities.
7.	**CAPACITY BUILDING FOR RADIOACTIVE WASTE AND SPENT FUEL MANAGEMENT – EXPERTISE, TRAINING AND SKILLS**	**SA2**	ENRESA should consider ensuring that the strategy and mechanisms are in place to avoid the loss of knowledge and know-how on radioactive waste and spent fuel management.
		RA5	ENRESA should re-evaluate the adequacy of R&D funding needed to support the step-by-step development of the Deep Geological Disposal programme.

APPENDIX D: IAEA REFERENCE MATERIAL USED FOR THE REVIEW

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Fundamental Safety Principles, Safety Fundamentals No. SF-1, Vienna (2006).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements No. GSR Part 1 (Rev. 1), Vienna (2016).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, General Safety Requirements No. GSR Part 2, IAEA, Vienna (2016).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4, IAEA, Vienna (2009).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Disposal of Radioactive Waste, IAEA Safety Standards Series No. SSR 5, IAEA, Vienna (2011).

[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Fuel Cycle Facilities, IAEA Safety Standards Series No. NS-R-5 Rev. 1, IAEA, Vienna (2014).

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Energy Basic Principles, Nuclear Energy Series, NE-BP, Vienna (2008).

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Radioactive Waste Management and Decommissioning Objectives, Nuclear Energy Series, NW-O, Vienna (2011).

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Fuel Cycle Objectives, Nuclear Energy Series, NF-O, Vienna (2013).

[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Policies and Strategies for Radioactive Waste Management, IAEA Nuclear Energy Series No. NW-G-1.1, IAEA, Vienna (2009).

[15] INTERNATIONAL ATOMIC ENERGY AGENCY, Policies and Strategies for the Decommissioning of Nuclear and Radiological Facilities, IAEA Nuclear Energy Series No. NW-G-2.1, IAEA, Vienna (2012).

[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Policy and Strategies for Environmental Remediation, IAEA Nuclear Energy Series No. NW-G-3.1, IAEA, Vienna (2015).

[17] INTERNATIONAL ATOMIC ENERGY AGENCY, Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, IAEA International Law Series No. 1, IAEA, Vienna (2006).

[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Glossary – Terminology used in Nuclear Safety and Radiological Protection, IAEA, Vienna (2007).

[19] Official Journal of the European Union No. L 199/48 from 2nd Aug 2011, COUNCIL DIRECTIVE 2011/70/EURATOMEURATOM of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste, Brussels (2011).