



**INTEGRATED  
REGULATORY  
REVIEW SERVICE  
(IRRS)  
FOLLOW UP MISSION  
TO  
SPAIN**

**Madrid, Spain**

*24 January to 1 February 2011*



**DEPARTMENT OF NUCLEAR SAFETY AND SECURITY**



## **REPORT**

### **INTEGRATED REGULATORY REVIEW SERVICE (IRRS)**

### **FOLLOW-UP REPORT TO THE GOVERNMENT OF SPAIN**

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**FOLLOW-UP REPORT TO**  
**THE GOVERNMENT OF SPAIN**  
**Madrid, Spain**

**Mission date:** 24 January to 1 February 2011

**Regulatory body:** Spanish Nuclear Safety Council (CSN)

**Location:** CSN Headquarters, Madrid, Spain

**Regulated facilities and practices:** *Nuclear power plants, fuel cycle facilities, medical and industrial sources, research applications, waste facilities, decommissioning and remediation, communication and public information.*

**Organized by:** International Atomic Energy Agency (IAEA)

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**The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.**

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## EXECUTIVE SUMMARY

At the request of the Government of Spain, an international team of 23 Senior Regulators in nuclear, radiation, transport, waste safety and nuclear security visited the Spanish Nuclear Safety Council (Consejo de Seguridad Nuclear CSN), in January 2008 to conduct a full scope Integrated Regulatory Review Service (IRRS) mission. The purpose of the mission was to undertake a peer review of the regulatory framework of Spain against the IAEA Safety Standards and to exchange information and experience on safety regulation. CSN is the only competent body in matters pertaining to nuclear safety and radiation protection in Spain and it has a key role with regard to nuclear security.

In April 2009, the Spanish Government requested a Follow-up IRRS mission, to review the progress in implementing improvements resulting from recommendations and suggestions made in the IRRS 2008 mission and reviewing the areas of significant regulatory changes since the last mission. Those areas where no suggestions or recommendations were made on 2008 IRRS mission were not included in the scope of the follow-up mission.

The review was conducted from January 25<sup>th</sup> to February 1<sup>st</sup>, 2011 and the review team comprised of five senior regulators from four Member States, two staff member from the IAEA and an IAEA administrative assistant. CSN had submitted to the IAEA, in advance of the mission, an information package on a dedicated CSN extranet web-site, including a comprehensive action plan for improving its regulatory effectiveness considering the 2008 recommendations and suggestions. The IRRS activities took place at the CSN headquarter in Madrid and it included a series of interviews and discussions with the CSN counterparts.

The team concluded that the recommendations and suggestions from the 2008 IRRS mission have been taken into account systematically by a comprehensive action plan. Significant progress has been made in several areas and many improvements were carried out following the implementation of the action plan including the completion of the revised CSN Statute.

During this follow-up mission the IRRS team determined that 4 of the recommendations and 23 of the suggestions made by the 2008 IRRS mission had been effectively addressed and therefore could be considered closed. CSN should be commended for this accomplishment. For the remaining recommendation and suggestions made, CSN has made progress but has not completed all the necessary actions and consequently these findings have been left open. The IRRS team also concluded that CSN should continue the implementation of this action plan and its monitoring through to completion.

In addition to the strengths identified during the 2008 mission, the IRRS team during the 2011 mission made note of the following strengths:

- The CSN improved its organization and policies related to the inspection activities and public communication as a consequence of the lessons learned from the event at the Asco Nuclear Power Plant;
- CSN's interactions at the highest level with licensees to discuss strategic planning and their investments in safety and human resources;
- the establishment of formal frameworks for cooperation between the CSN and several governmental organizations such as the Ministry of Health and the Ministry of Interior in the areas of radiation protection and security ;
- The arrangement for a transparent and technically sound siting process for the central temporary storage facility and its associated technical centre;
- The strong support of the senior management and staff participation, in the internal audit process.

This report also includes recommendations and suggestions to further strengthen the regulatory body in Spain and to support the observed improvement activities.

- The need to establish a formal policy for the use of a standing or ad hoc technical advisory body in case of complex technical regulatory decisions;
- The CSN should continue to work with relevant competent authorities and other bodies to facilitate the process for siting a disposal facility for spent fuel and high level waste.
- CSN should continue its efforts to manage internal organizational changes
- The CSN should continue to work with relevant competent authorities and other bodies to complete the regulatory framework for security of radioactive sources and security of information.

CSN staff put significant effort into the preparation for the mission. During the review the administrative and logistical support was excellent and the team was extended full co-operation in technical discussions with CSN personnel. CSN counterparts were enthusiastic and were interested in obtaining further advice relating to the way they conduct their work, and their plans for further development.

## I. INTRODUCTION

### **BACKGROUND**

In 2008 at the request of the Spanish Government, an IAEA team of eighteen experts and two observers from Member States, three staff members from the IAEA and an IAEA administrative assistant visited the Spanish Nuclear Safety Council (Consejo de Seguridad Nuclear - CSN), from 28 January to 8 February, 2008 to conduct a full scope Integrated Regulatory Review Service (IRRS) mission to review the CSN regulatory framework and its effectiveness. The purpose of the mission was to conduct a full scope IRRS mission to review the Spanish legal and governmental infrastructure for nuclear, radiation, radioactive waste and transport safety and the physical protection of nuclear installations and the effectiveness of the Spanish regulatory body (CSN) and to exchange information and experience among CSN and the IRRS team with a view to contributing to harmonizing regulatory approaches and creating mutual learning opportunities among senior regulators.

The selected areas reviewed were: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; safety of radioactive sources; emergency preparedness; radioactive waste management, decommissioning, remediation; transport; emergency preparedness; the management system and public information and communication. The IRRS Mission to Spain included for the first time a module on nuclear security to review the security of nuclear and radioactive material in use, storage and transport.

In 2008 the IRRS activities took place mainly at the CSN headquarters, Madrid. The mission included a series of interviews and discussions with key personnel at CSN and at other organizations with a view to observing regulatory activities and the effectiveness of the system. Interviews and discussions took place with: staff at the Ministry of Industry, Tourism and Commerce; the Ministry of the Interior; and CIEMAT (Centro de Investigaciones Energeticas Medioambientales y Tecnologicas); with plant managers and staff of operating organizations of NPPs, with emphasis on safety and physical protection; with staff at fuel cycle facilities; industrial facilities (accelerators/irradiators and industrial radiography facilities); medical facilities (for radiotherapy, nuclear medicine and diagnostic radiology); ENRESA (Empresa Nacional de Residuos Radiactivos) radioactive waste repository (El Cabril); and decommissioning and remediation organizations including a mining site; and with staff carrying out an emergency response drill (Ascó NPP).

The report was published in 2008 and it was made publicly available at the CSN and IAEA websites.

### **FOLLOW-UP MISSION**

In April 2009 the Spanish Government requested a Follow-Up IRRS mission, to review the measures undertaken following the recommendations and suggestions presented in the report of the 2008 IRRS mission, which mainly focussed on the review of the recommendations and suggestions from the 2008 mission.

The review was conducted from 25 January to 1 February 2011 and consisted of 5 senior regulatory experts from 4 Member States, two staff members from the IAEA, and an IAEA administrative assistant (Appendix I). IRRS activities took place at the CSN offices Madrid, Spain.

## II. OBJECTIVE AND SCOPE

The purpose of the IRRS follow-up mission was to continue the work of improving regulatory effectiveness by reviewing the CSN's progress in response to IRRS mission recommendations and suggestions, identification of new good practices and to exchange information and experience among CSN counterparts and the IRRS team with a view to contributing to harmonizing regulatory approaches and creating mutual learning opportunities among regulators.

The IRRS mission was structured in order to take into account the progress in implementing improvements resulting from recommendations and suggestions made in the IRRS 2008 mission and reviewing the areas of significant regulatory changes since the last mission.

Those areas where no suggestions or recommendations were issued on 2008 IRRS mission were not included in the scope of the follow-up mission.

The general key objectives of the IRRS mission are to enhance the regulatory effectiveness by:

- Providing the host country (regulatory body and governmental authorities) with a review of their regulatory issues, in particular those highlighted in the 2008 mission;
- Providing the host country with an objective evaluation of their regulatory practices with respect to international safety standards;
- Contributing to the harmonization of regulatory approaches among Member States;
- Promoting sharing of experience and exchange of lessons learnt;
- Providing key staff in the host country with an opportunity to discuss their practices and action plans considering the 2008 findings with reviewers who have experience of other practices in the same field;
- Providing the host country with recommendations and suggestions for improvement;
- Providing other States with information regarding new good practices identified in the course of the review;
- Providing reviewers from States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field ,in particular on how the host country is implementing the improvements; and
- Providing the host country through completion of the IRRS self-assessment of a comparison of its activities against IAEA safety standards and thereby identifying potential areas for improvement their action plan.

### **III. BASIS FOR THE REVIEW**

#### **A) PREPARATORY WORK AND IAEA REVIEW TEAM**

The preparatory work for the mission was carried out by the IRRS IAEA Coordinator Mr Gustavo Caruso, Section Head-Nuclear Safety of Nuclear Installations NSNI/ IAEA and the appointed Liaison Officers, the two Technical Director Mr Juan Carlos Lentijo and Ms Isabel Mellado.

An IRRS preparatory meeting was held on 19-20 May 2010 to discuss the technical and administrative details of the follow up mission to Spain. It took place in the Spanish Nuclear Safety Council (CSN) offices in Madrid, Spain with the participation of the appointed IRRS Team Leader Mr Luis Reyes, Senior Executive from the United States Nuclear Regulatory Commission (USNRC) and Mr Gustavo Caruso, the IAEA IRRS coordinator. During this preparatory meeting the CSN was informed that the 2008 IRRS Team Leader Mr Ulrich Schmocker could not participate in the Follow up mission due to personal reasons. The IRRS Review Team and the CSN acknowledge the valuable contribution of Mr Ulrich Schmocker in the conduct of the 2008 IRRS Mission to Spain.

The preparatory meeting was opened by Ms Carmen Martinez Ten, President of the Spanish Nuclear safety Council (CSN) and Mr Antoni Gurgui, CSN Commissioner, who provided an organizational overview and the main issues and changes to the Spanish regulatory regime. All the preliminary organizational aspects of the mission were defined during the preparatory meeting with the participation of Ms Martinez Ten, Mr Antoni Gurgui, Ms Isabel Mellado and Mr Juan Carlos Lentijo

During the preparatory meeting discussions it was agreed that the advance reference material (ARM), including the output from the self-assessment, would be provided to the IAEA in November 2010. In addition, the scope of the follow-up IRRS mission was agreed to include: progress made to address the 2008 IRRS mission findings and considering the changes since 2008 mission in those areas where recommendations or suggestions were issued. The ARM and the main agenda items were discussed and agreed.

In accordance with the request from CSN, and taking into account the scope of the Follow up mission as indicated above, it was agreed that the IAEA review team would comprise of 5 Senior regulators from 4 Member States (namely Australia, Norway, United Arab Emirates and the United States of America,) who already participated in the 2008 mission, under the IAEA coordination and an IAEA administrative assistant (see Appendix I). The working areas and the CSN counterparts were nominated as outlined in Appendix III.

During the preparatory phase all documents comprising the ARM were made available to the IAEA review team through a dedicated web-site. In particular, the main document about the status of actions related to recommendations and suggestions from 2008 IRRS mission were provided

The reviewers and the IAEA staff prepared before the mission the initial impressions on the ARM, reviewed the CSN's action plan and prepared for the interviews during the mission with the counterparts.

An initial IAEA team meeting took place on Monday 24<sup>th</sup> January 2011 and was attended by the IRRS Review Team and the CSN Liaison Officers, Ms Isabel Mellado and Mr Juan Carlos Lentijo. The IRRS Team Leader and the IRRS IAEA Coordinator discussed specific aspects of the mission and the background and main issues from the IRRS in 2008, the basis for the review, context and objectives of the IRRS and IRRS methodology for the review and the evaluation were also agreed among all of the mission reviewers. The Liaison Officer presented the logistical and other aspects of the follow-up mission.

#### **B) REFERENCES FOR THE REVIEW**

The main reference documents provided by CSN for the review mission are indicated in Appendix VI. The most relevant IAEA Safety Standards and other reference documents used for the review are indicated in Appendix VII.

### **C) CONDUCT OF THE REVIEW**

The entrance meeting was held on Tuesday, 25<sup>th</sup> January 2011 with the participation of Ms Carmen Martinez Ten, CSN President, Mr Antoni Gurgui, CSN Commissioner, Mr Javier Arana from the MITyC, Mr Jaime de Ponga, MITyC, Ms Isabel Mellado, CSN Technical Director for Nuclear Safety, Mr Juan Carlos Lentijo, CSN Technical Director for Radiation Safety and other participating CSN staff contributing to the follow up mission.

Opening remarks were made by Mr Gurgui, Ms Martinez Ten, Mr Caruso and Mr Reyes. Several presentations were carried out and discussed during the Entrance meeting. The status of implementation of recommendations and suggestions was discussed in detail in order to understand the current situation and delineate the initial main areas to be discussed during the interviews with the counterparts. In addition, as a complementary information, the CSN outlined a new epidemiological study as one significant activity completed by CSN and Carlos III Health Institute in order to estimate the doses to the population from the operation of nuclear and radioactive fuel cycle installations and those from natural radiation.

During the mission, a systematic review was conducted of all recommendations and suggestions from the IRRS in 2008 with the objective of establishing progress by CSN in response to the 2008 mission, as well as identifying new good practices for the review stated in the scope of the mission. The review was conducted in topical areas taking into account the previous experience of the experts in the 2008 mission, through meetings, interviews and discussions with CSN personnel and assessment of the action plan. The team performed its activities in accordance with the Mission Programme, outlined in Appendix II.

The exit meeting was held on Tuesday, 1<sup>st</sup> February 2011 with the participation of Ms Martinez Ten, CSN President, Mr Antoni Gurgui, CSN Commissioner, Ms Isabel Mellado, CSN Technical Director for Nuclear Safety, Mr Juan Carlos Lentijo, CSN Technical Director for Radiation Safety, all Deputies Directors, all counterparts and the CSN's management staff.

The main conclusions of the follow-up IRRS mission were presented by the IRRS Team Leader Mr Luis Reyes and closing remarks were made by Mr Denis Flory, IAEA Deputy Director General – Department of Nuclear Safety and Security and by Mr Carmen Martinez Ten, CSN President.

The draft technical notes were handed over to CSN at the end of the meeting.

## 1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

### 1.2 LEGISLATIVE

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

- S1 **Suggestion:** The CSN should consider, in line with the practice adopted in other countries, whether to propose a change in the Law on Fees and Public Prices that would apply a base annual fee and charges for regulatory activities generated by licence holders so as to establish a 'price signal' for operators.
- S2 **Suggestion:** In implementing the new legal provisions for the operation of the advisory committee on transparency and communications, the potential for there to be unintended adverse impacts of transparency and communications on safety should be carefully considered by CSN and debated with the advisory committee.

#### Findings from the 2011 Follow-Up Mission

**Suggestion 1:** The CSN has commenced a complete review of the fee schedule established under the Law on Fees and Public Prices for services Rendered by the Nuclear Safety Council. The fee structure was last established by Law 14/1999 and the current revision is designed to reflect better the CSN's current activities. The review is being overseen by a committee of senior CSN staff, reporting to the CSN's standing committee on human and general resources, which is chaired by a Commissioner.

As a part of this review, working documents have been prepared examining the CSN's regulatory activities in detail and comparing them with the existing fee schedule. Proposals for responding to S1 are being considered as a part of this overall process – with regard to NPPs, the proposal under consideration would impose fees on operators requiring supplementary inspections as a result of findings under the reactor oversight process or reactive inspections due to operational events. The way in which S1 might apply to other facilities is also under active consideration in the context of the review.

The CSN staff advise that it is hoped that a complete proposal will be ready and approved by the Commission by the end of 2011. It will then be necessary to submit the proposal to wider Government consideration and for decision as to what the Government may wish to propose to the Parliament and when.

The Suggestion dealt with just one aspect of the CSN's fee structure, which is established in Law. A change in a Law is clearly a serious and lengthy matter. Therefore, It is entirely appropriate that consideration of S1 is taking place within the context of an overall review of the fee schedule. It is clear from the working papers noted by the Mission, that S1 is being properly considered as a part of this review.

#### **Suggestion 1 (S1): is closed.**

**Suggestion 2:** The advisory committee referred to in Suggestion 2 (The Advisory Committee for public information and participation) has now been established with its terms of reference and operating procedures established under the new Statute of the Nuclear Safety Council that came into effect in November 2010. Its stated functions are: issuing recommendations for the CSN to guarantee and improve transparency; and suggesting to the CSN measures promoting the access to information and the participation of the population in those matters within the CSN's jurisdiction.

The committee is to meet first on 24 February 2011. The agenda distributed to the committee for its first meeting includes an item entitled as follows:

*'CSN's activities concerning information and public participation relating to nuclear safety and radiation protection. Suggestion (S2) of the IAEA on the impact of transparency on safety.*

In other developments, the CSN Instructions on events required to be reported to the Council (IS-10 for Nuclear Facilities and IS-18 for Radioactive Installations), which forms the basis for the CSN in turn to bring matters to public attention. IS-10 has been re-drafted and is currently with licensees for an initial round of comments. After further review by the CSN, the revised draft Instructions will be subject to formal consultation before being brought into force.

The CSN has also established a Procedure for public communication of events and special information (PG.II.06) within its management system. This document provides for certain events reported to the CSN to be reported by CSN to the public by means of a press release sent to media and institutions for certain defined categories of event with other defined events reported only through the CSN website.

The CSN meets annually with the top-level management of each NPP licensee to discuss strategic matters significant for safety. These matters include the licensee's policies on transparency and communications as well as its policies on investment, safety improvements, and human resources. As a consequence of these meetings including open discussions on communication policy and its potential impact on safety, the NPP licensees have committed to greater transparency and enhanced communication with the public. All have improved their human and material resources in communications through such means as setting up communication units and establishing websites.

The establishment of advisory committee referred to in S2 and the inclusion of the agenda item quoted above for the first meeting, shows that the CSN is commencing to implement this aspect of the suggestion. The CSN has continued to address the issues that prompted the Suggestion in the context of its own work on public communication in regard to the reportable events Instruction and the procedure on public communications. The Council has also encouraged nuclear facility operators to improve their own public communications, including through the annual high-level meetings. It is notable that all the NPPs now have their own website.

The 2008 mission report specifically referred to the reporting of 20% power reductions and the possibility that this might lead operators to reduce power less than 20% in certain circumstances resulting in higher worker doses. The CSN continues to include power reductions as reportable event, which also results in the issuing of a press release by CSN. An example of such a press releases was noted to be very straightforward and simple, pointing out the reason for the reduction and giving assurance of no safety implications. The very routine nature of such communications should work to establish a view that this is ordinary business that the public is being informed about – not a sensational story that is concealed from them. The utilities are also being encouraged to announce these observable events themselves prior to the CSN doing so.

The matter of communications and transparency and possible impact on safety is, of course, an ongoing issue for CSN and all regulators. The matter is clearly being addressed as part of the work of the new advisory committee and it is a background to CSN's ongoing regulatory and communication processes.

**Suggestion 2 (S2): is closed.**

### **New findings from the 2011 Mission**

There were no new findings in the 2011 IRRS Follow up Mission.

## **2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**

There were no findings in this area in the 2008 IRRS mission

### 3. ORGANIZATION OF THE REGULATORY BODY

#### 3.2. STAFFING AND TRAINING

##### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

- S3 **Suggestion:** CSN should consider an approach that will facilitate the recruitment of staff at above the base-level for technical staff and non technical professionals.
- S5 **Suggestion:** The plans to enhance the organizational expertise in risk assessment, operating experience and human organization factors should be implemented with high priority. Other resource skill allocations should consider new facilities being proposed as well as the new demands in security, communications, international relations and compliance with law 33/2007 regarding radiation protection of patients.
- S6 **Suggestion:** The training of CSN inspectors should consider the addition of soft skills training such as communications, report writing and conflict resolution.

##### Findings from the 2011 Follow-Up Mission

**Suggestion 3:** The 2008 Mission put forward Suggestion S3 on the following grounds (page 44):

*It is difficult to recruit staff at above the base level. This may become a more important issue for the CSN to face as it seeks to replace the cohort of senior staff entering retirement. Further, staff with relevant professional qualifications outside nuclear engineering and radiological science may not be able to be employed as civil servants in the CSN. One example is staff with qualifications in psychology, important for dealing with issues of human factors and safety culture. The team recognizes that changes in this area must be consistent with developments in the Spanish public sector employment as a whole, but nonetheless believes that it deserves continuing attention.*

The CSN has continued to use the measures available to it as a part of the Spanish civil service administration to address the issues that lead to the 2008 Mission putting forward Suggestion S3. Where the need for above base-level recruitment is identified, the position is advertised throughout the Spanish civil administration (which includes other technical and health organizations). Some recent examples of such above base-grade recruitment quoted by CSN staff included the recruitment of a senior level person with certain IT-related skills and of another senior person with particular knowledge of shielding calculation codes. It is also possible for the CSN to use contractors or the general labour law to engage staff for certain activities that do not involve the exercise of powers of the State and these mechanisms have been used on occasion.

CSN staff affirmed that as a part of Spain's civil administration, it is not possible within the long-standing legal arrangements to recruit generally above the base-level. The staff put the view that it is not appropriate or desirable that the CSN somehow seek to be exempt from or placed outside the Spanish civil administration.

With regard to the replacement of retiring staff, the CSN managers are continuing to deal with this as a part of their ongoing managing of the organization – for example, by positioning younger staff into positions where they can be trained and mentored by staff due to retire. The new Statute also formalizes a role for a Research and Knowledge Management Unit that, inter alia, is responsible for the development and promotion of knowledge management within the organization and the preparation of technical training programmes in nuclear safety, radiation protection and physical protection and evaluation of their results.

With regard to the particular example of a need for psychology qualifications referred to in the 2008 Mission report, such a person happened to be able to be recruited through base-level recruitment (the person also had technical qualifications).

The team continues to be of the view that it ideally would be desirable for the CSN to have a wider ability to recruit staff above base level. However, as noted in the 2008 Report, this is a matter derived from Spanish public sector employment as a whole and is outside the CSN's control.

#### **Suggestion 3 (S3): is closed.**

**Suggestion 5:** The overall resource context for the CSN, of course, changed during the period as a result of the economic crisis. The CSN recruited 11 new technical staff in 2008 and 4 in 2009. It has not been able to recruit new staff in 2010 and it is unlikely to be able to do so this year. Nonetheless, the CSN has been able to devote additional resources to the areas named in Suggestion 5 with the exception of the radiological protection of patients. In this area, an agreement on roles and responsibilities has been reached with the Ministry of Health and the CSN's activities will be undertaken in a unit redeploying existing staff. This is a part of a re-organisation of the two Technical Directorates that is close to being finalized. The proposals in the draft re-organisation reflect the directions set in the new CSN Statute and are consistent with the Suggestion 5.

The senior managers in the CSN are managing their resources very effectively and consistent with the directions set out in the new Statute and reflected in Suggestion 5. This is being done in a very different environment than that which existed at the time of the 2008 Mission and the senior CSN staff are to be commended for their effectiveness in this changed environment.

#### **Suggestion 5 (S5): is closed.**

**Suggestion 6:** The CSN training programme in 2009 and 2010 offered training in all the soft skills mentioned in Suggestion 5. These training courses were offered by contractors to CSN. Importantly, training in these skills are a part of a new systematic approach to training developed by CSN and which is reflected in the 2011 training programme. In addition, the CSN is in the process of building a competency framework following the approach laid down in the IAEA TECDOC 1254. This will cement the intent of Suggestion 6 into the framework of management of CSN.

This suggestion has been very clearly and thoroughly taken up by CSN.

#### **Suggestion 6 (S6): is closed.**

### **New findings from the 2011 Mission**

There were no new findings in the 2011 IRRS Follow up Mission.

### 3.3. ADVISORY BODIES

#### **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION**

S7 **Suggestion:** CSN should use its authority to establish a technical advisory committee.

#### **Findings from the 2011 Follow-Up Mission**

The text of the 2008 report on this topic is as follows:

##### Advisory Bodies

*CSN has the authority to establish Technical Advisory Bodies. They do not have a permanent technical advisory body as is customary by many Regulatory Organizations. A temporary technical*

*advisory group was established after the Vandellos II event to advise CSN with respect to this event. A recent advisory committee was mandated by Law to provide advice to CSN regarding transparency of their activities. These recent mandated changes and increases in the size of the organization have raised questions with the structure of the organization specifically with respect of the high level structure. While the organizational structure is best defined by the regulatory organization based on the country Government structure and processes, it is customary by mature regulatory organizations to have a technical advisory group to enhance technical decision making. The technical advisory group is typically a part time group consistent of technical subject matter experts.*

The CSN Law allows the CSN to establish technical advisory committees and this power has been substantially elaborated upon in the recently approved CSN Statute.

An advisory committee was established and operated in 2006-2010 to oversee the recent epidemiological study of health around NPP sites that was carried out by a health research agency in cooperation with CSN.

The CSN has also continued to operate three 'forums' for radiation protection: medical sector; industrial sector; and for radiation protection services. Each of these forums comprises CSN staff and radiation protection professionals from the different sectors. These forums allow for dialogue and exchange of information including on the practical implementation of regulatory requirements and the development of new rules, requirements and recommendations in the respective fields.

As required, the CSN seeks technical advice from external experts on specific issues, particularly through a standing agreement with CIEMAT. Recent examples that were brought to the Mission's attention included:

- Neutron flux noise analysis of an NPP
- Metallurgical destructive examination of equipment at an NPP.

The high technical expertise of CSN staff is acknowledged as is the willingness and ability of CSN to seek external expert assistance on specific issues to assist CSN staff in their evaluation. The CSN has not, however, formally considered the establishment of an ongoing technical advisory group with the intention of enhancing technical decision-making, which this mission believes was the intention of Suggestion 7.

After discussion with counterparts, who asserted that the full intent of Suggestion 7 was not clear and taking into account the work undertaken by CSN to establish mechanisms for technical advisory committees, the mission agreed that the Suggestion should be amended as discussed below.

**Suggestion 7 (S7): is amended.**

### **New findings from the 2011 Mission**

The mission takes the view that the process of seeking external expert advice to assist the CSN in reaching regulatory decisions should be formalized. In undertaking this formalization, the CSN should consider the range of possible options for establishing channels through which such expert external advice may be obtained.

### **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011 FOLLOW UP MISSION**

- (1) **BASIS:** Requirement 20 of GSR Part 1 states that *'The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities.'*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011  
FOLLOW UP MISSION**

SF1 **Suggestion:** That the CSN establish a formal policy establishing the circumstances in which it will consider seeking external expert advice to assist the Council in making regulatory decisions, including through the establishment of a standing or ad hoc technical advisory bodies.

## 4. ACTIVITIES OF THE REGULATORY BODY

### 4.3 DEVELOPMENT OF REGULATIONS AND GUIDES

#### 4.3.1. Nuclear Facilities

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

- S8 **Suggestion:** The planned CSN policy and overall strategy for the development of binding regulations and guides should be developed in the near future. It should respond to needs identified and experience made with the current activities to further enhance consistency and completeness of the Spanish ‘regulatory pyramid’. The approach should ensure that the requirements imposed by the regulator do not relieve the operator of its prime responsibility for safety.
- S9 **Suggestion:** CSN should compile a uniform glossary to be used for illegally based regulatory documents. This glossary should also enable and support the proper understanding or interpretation of the respective language used in the countries of origin, as well as in IAEA standards.
- S10 **Suggestion:** Regarding major backfittings, the state of the art of backfitting technology for comparable designs in other countries – not only the countries of origin – should be taken into account for more detailed conditions and requirements to the licensees.
- S11 **Suggestion:** CSN should address possible inconsistencies for Spanish regulations resulting from requirements from foreign sources as the countries of origin of design or the IAEA more directly. The experience made with the integration of different sources into the Spanish system of regulations and guides should be reported back for consideration by the respective institutions to promote resolution of such inconsistencies.

#### Findings from the 2011 Follow-Up Mission

**Suggestion 8:** CSN has developed a strategy document that incorporates guidance determining what standards development should be at CSN in the fields of nuclear safety, spent fuels, dismantling, radioactive waste management, transportation, radiation protection, radioactive facilities, emergencies and physical protection. The document “Strategy for Guides and Regulations Preparation” considers the following items:

- Identification of needs;
- Sources and references for the development of new guides on regulations;
- Action plan for guides and regulations development and revision.

A three year plan for mid-term guides and regulations development and a working annual plan have been approved.

The strategy document is undergoing legal review as the last step before submittal for final approval. An analysis was completed comparing the CSN requirements to international safety standards and safety guides in the nuclear safety field.

**Suggestion 8 (S8): is closed on the basis of progress and confidence.**

**Suggestion 9:** A technical glossary was prepared that support the proper understanding or interpretation of the respective language which includes language used in the countries of origin as

well as in IAEA standards. A review of the CSN documents and guides using the glossary was completed. The review identified inconsistencies that are being clarified by harmonizing the affected documents. The glossary is in the final stages of approval and will become public in the intranet of CSN. The technical glossary is a living document that will be updated periodically as the need arises.

**Suggestion (S9): is closed on the basis of progress and confidence.**

**Suggestion 10:** CSN is preparing a procedure that formalizes the requirement of considering technology for comparable designs in other countries. This practice has been implemented in the process for license renewal for two facilities. Also the technical staff visited a facility outside the country of origin to review the state of the art of backfitting for applicability to a similar facility in Spain.

In the decennial license renewal granted for two plants in 2010 requirements on severe accident management based on WENRA reference levels, as well as reports elaborated by international working groups that summarize the state of the art on the matter were included.

Bilateral exchanges of information with regulators which have in their country NPPs similar to Spanish ones have been started in order to obtain information as to what improvements respect to the original design were implemented in this plant, either on the licensee initiative or upon regulatory requirement.

In addition to that, a comparison of the content and scope of periodic safety reviews with other European countries will be conducted.

Since the IRRS 2008 Mission the CSN has emphasized the use of other sources of information, in addition to the country origin of the technology, when making decisions about major back fittings.

The first additional source is the knowledge of CSN staff acquired from its participation at different international committees. CSN staffers belong to almost all technical committees run by IAEA, NEA, WENRA, etc. where significant operating experiences of NPP are shared, major new standards and regulation are discussed. A good example is the field of “severe accident” management, where the requirements imposed to Spanish NPPs in the decennial license renewal granted for two plants in 2010 are based on WENRA reference levels, as well as reports elaborated by international working groups that summarize the state of the art on the matter.

The second additional source is bilateral exchange of information with regulators that have in their country NPP similar to Spanish ones. This exchange of information ranges from telephone calls, e-mailed questions to formal meetings. E.g., CSN organized a visit to the Swiss nuclear regulator, ENSI, and the Swiss NPP of Mühleberg, rather similar in design and vintage to Garoña NPP, in order to obtain information as to what improvements respect to the original design were implemented in this plant, either on the licensee initiative or upon regulatory requirement. The experience was very useful, especially due to the supportive attitude of both ENSI and the licensee

The new CSN practice of requiring in the Periodic Safety Review the analysis of modern standards not directly applicable to the operating plants (“standards of conditioned application”) are not appropriately reflected in the Safety Guide 1.10 on the periodic safety review. Consequently, once the current series of renewals of plant operating licenses is completed, a review of the Safety Guide will be started and a comparison of periodic safety reviews with other European countries will be conducted.

**Suggestion (S10): is closed on the basis of progress and confidence.**

**Suggestion 11:** Procedure PG.III.03 was prepared, approved and is currently implemented. This procedure requires a review for possible inconsistencies for Spanish Regulations resulting from requirement from foreign sources as the countries of origin of design or the IAEA.

The new procedure includes the need to communicate to the regulatory body any inconsistency detected in the regulations regarding to the international organisms or to the regulatory bodies of other country with competence in this matter.

This procedure is applicable to all the regulation, whether it is issued by the CSN, as Safety Instructions and Safety Guides, and whether it is issued by other Spanish Ministries in which the CSN takes part.

**Suggestion 11 (S11): is closed.**

### New findings from the 2011 Mission

There were no new findings in the 2011 IRRS Follow up Mission.

#### 4.4. INSPECTION AND ENFORCEMENT

##### 4.4.1. Nuclear Facilities

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

- S12 **Suggestion:** CSN should evaluate the effectiveness of the new SIC'S inspection programme together with the other inspection, review and assessment activities with respect to the coverage of the issues and activities important to safety.
- S13 **Suggestion:** CSN should consider the balance of the resources allocated to the human and organizational issues as well as the number of inspections in which these issues are addressed. In planning inspections of human and organizational factors, CSN should also consider what is an appropriate level and way of addressing management and policy issues of the licensees.
- R1 **Recommendations:** CSN should implement a systematic way of compiling and presenting the results obtained, the trends and consequences drawn from inspections and review and assessment for all nuclear installations where applicable, and should give feedback to the licensee. This should be undertaken on a periodic basis.
- S14 **Suggestion:** As inspection reports of the nuclear power plants and fuel fabrication facility as well as the SIC'S information package are being put onto the CSN web site, CSN should have a standard format for presenting the scope of the inspections and the findings together with its evaluation of the safety significance and the information of the nuclear power plant should be in one place. CSN should also assess the benefit of presenting inspection reports with utility comments and their resolution at the web site.

### Findings from the 2011 Follow-Up Mission

**Suggestion 12:** CSN has completed a self evaluation of the new SISC inspection programme which included other inspections, review and assessment activities with respect to the coverage of the issues and activities important to safety. The assessment identified the need to supplement the inspection programme with an additional inspection on the subject of operating experience. This inspection was added and subsequently performed at all NPPs. Self assessments will be conducted every two years in accordance with procedure PA.IV.207.

In addition a review of station PRA analysis has been included in the inspection programme to make sure that the important risk components and activities are inspected in a periodic basis. The first inspection in this area is scheduled to be performed at the Almaraz NPP.

**Suggestion 12 (S12): is closed.**

**Suggestion 13:** CSN has changed its organization to include a unit dedicated to the inspection and assessment of human and organizational issues. This new unit has been staffed with experienced

experts from within CSN and with additional new recruited personnel. CSN's instruction IS-19 issued in 2008 required licensees to implement a management system in accordance with the IAEA requirement GS-R-3.

An analysis has been performed (DSN/SG/11/08) to identify the way in which the different parts of the licensee's management system are overseen by CSN, including the management and policy issues of the licensees. The high level annual meetings of the CSN plenary with licensee senior management to address strategic and policy issues are an important element of this oversight.

**Suggestion 13 (S13): is closed.**

**Recommendation 1:** CSN has implemented a NPP performance assessment that has been expanded to include a systematic way of compiling and presenting the results obtained, the trends and consequence drawn from inspections and review and assessment.

The performance assessment is presented to the licensees in an annual basis. These activities are covered by procedure PG.IV.07 revised in 2010 and is currently being implemented.

Procedure PG.IV.07 was revised and formally approved to expand the extent of the licensee assessment by including a broad number of licensee performance issues, include significant findings, events as reported by INES scale, reportable incidents and changes to technical specifications.

CSN is also implementing a similar process for the two other nuclear installations in operation. The process has been completed for the Juzbado fuel facility and is being piloted through a working group at the Cabril waste facility.

**Recommendation 1 (R1): is closed.**

**Suggestion 14:** CSN has designed a modification to their web page to link inspections findings to the relevant inspection report. The modification has been approved and is implemented.

**Suggestion 14 (S14): is closed.**

**New findings from the 2011 Mission**

CSN requires licensees to provide their strategic plan with the associated investments and human resources needs for the following four years. Every year licensees update and report to CSN necessary changes. These changes are discussed in detail with the CSN plenary and licensee top executives.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011 FOLLOW UP MISSION**

- (1) **BASIS:** GSR Part 1 para 4.3 states that "The objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements. (f) Authorized parties have the human, organizational, financial and technical capabilities to operate facilities safety....."

**GPF1** **Good Practice:** CSN issued IS-19 instruction on the management system based on the IAEA GS-R-3. Under this framework the licensee's strategic plan with the associated investments and human resources needs for the following four years is submitted yearly to the CSN and discussed in a high level meeting between the CSN plenary and the licensee senior management.

#### 4.4.2. Radiation Facilities – Industrial and Medical Practices, Radiation Protection and Dosimetry Services

### ECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

- R2 **Recommendation:** From all its inspections in x-ray diagnostic and radiation facilities, CSN should build and express an opinion about the results obtained, the trends and consequences drawn in the different practices using radioactive sources, and to give feedback to the licensee. This should be undertaken in a periodic way.
- S15 **Suggestion:** CSN should consider to upgrade their internal procedures to a formal procedure for inspection of Dosimetry Services.

#### Findings from the 2011 Follow-Up Mission

**Recommendation R2:** CSN has carried out a quantitative and qualitative analysis of all the inspections performed both to radioactive facilities and X-ray medical diagnosis facilities. The scope of such analysis has been all the inspections performed by inspectors based at CSN headquarters as well as those performed by inspectors based in regional offices on behalf of Agreements in force between CSN and nine Spanish Regions. Results of mentioned analysis have been included in a report entitled *Report on results of yearly inspection program to radioactive facilities*.

The team went through the inspection program for 2010. According to the CSN policy all radiation facilities are inspected on annual basis, which includes radiation therapy, nuclear medicine, industry, research and education facilities. Authorized dosimetry services (STP) and radiation protection services (SPR) are inspected every third year. X-ray facilities are only object to registration, and about 1% of all X-ray facilities are inspected annually as they are under directly control by the radiation protection services. There are 17 regions in Spain; nine of them have regional offices in charge of inspections. CSN inspect the others, as well as all the SDP and most of the SPR. There is also a separate plan for the mandatory inspections in front of operating authorizations' and decommissioning. The inspections of radiation facilities alone accounted for as many as 1403 in 2010.

The team reviewed the *Report on results of yearly inspection program to radioactive facilities* from 2008 and 2009. We heard there had been throughout discussions on the template for the reports. The reports seem well structured with a foreword, aim and scope, dedicated chapters including findings from both ordinary inspections and before licensing inspections. On a general level the various findings were pinpointed. For example in the 2008 report it appeared that CSN had sent enforcement letters to 46 facilities, and done two sanctions. The reports also summarize the conclusions, some "lessons learned" and point at possible improvements for the future.

The reports however only include aggregated data and all facilities were thereby anonymous. We discussed the detail level in the report, whether it could include regional differences, or also whether the name of the facility should appear. We also discussed whether there were some mechanism for on periodical basis reviewing how the selection of inspection objects are prioritized, and also the scope of inspections, whether the most important matters are focused on during inspections, etc. We agreed that it is important now to gain some experience with the new procedure before these other matters can be considered in the future.

A new Technical Procedure, referenced as PT.IV.109 and with the title *Information about annual results from radioactive and X-ray facilities*, has been developed and incorporated to the CSN management system per 21.01.11.

**Recommendation 2 (R2) is closed.**

**Suggestion S15:** There is currently 22 dosimetry services in Spain, and they are inspected every third year by CSN. CSN has authorized one new internal dosimetry service since 2008, but in addition many of the services have got modifications of the equipments that have required reauthorisations. Two Dosimetry services have closed down because of expensive imposed corrective actions. Inter comparisons is emphasised as an important additional quality measure for the dosimetry services.

The team went through the new Technical Procedure, referenced as PT.VII.12 with title *Control inspection of external dosimetry services*. The team was introduced to the technical template for the procedures during the visit to CIEMAT external dosimetry laboratory in Madrid in 2008. The new procedures pretty much include this template for inspection, but in addition the procedure involves the planning process in front and the actions and follow-up. The team was introduced to the templates for letters sent in front of inspection and inspection report.

**Suggestion 15 (S15): is closed.**

### **New findings from the 2011 Mission**

During 2011 mission the team has been introduced to several examples where CSN has started a very good collaboration with other national authorities that may have overlapping mandates on specific areas. Two of these initiatives are related to medical practices and dosimetry services, and should be acknowledged:

It was referred in 2008 that according to the new Law 33/2007, of 7<sup>th</sup> November 2007 (Article I h) the CSN should collaborate with other competent authorities in issues related to radiation protection of people subjected to medical diagnosis or treatment procedures with ionizing radiation. It was emphasized that this collaboration needed to be clarified, to be sure that the requirements in the Medical exposure directive 97/43 Euratom can be met in the overall Spanish legislation. An internal working group has been set up on the subject. *A Framework co-operation agreement between the Ministry for Health and the CSN has been signed in 2010.* The six page paper includes the framework of cooperation and involves radiation protection issues in general, training of staff, emergency preparedness, the quality of drinking water etc. In Spain the direct responsibility for the management of operational aspects related to patient radiation protection relies on the health authorities in each of the 17 Spanish regions (Comunidad Autónoma). CSN should be encouraged to develop this framework programme into operational level.

It was reported in 2011 that three of the dosimetry laboratories were being accredited according to ISO norms by the National accreditation body (ENAC). The CIEMAT, serving as a reference laboratory for the CSN (external dosimetry, internal dosimetry, SSDL with Co-60, Cs-137 and X-ray ISO radiation qualities), did apply for accreditation in 2009. In accredited laboratories the assessment will consist of verification of the quality accreditation. For laboratories without accreditation the assessment also covers the QA aspects prior to authorization. *A general co-operation agreement has been signed (2010) between CSN and the National Agency for Accreditation (ENAC) to work together for the accreditation of any kind of companies working in the field of nuclear energy and radiation protection.* It includes joint definition of accreditation requirements as well as participation of CSN in audits for accreditation and periodic audits for re-accreditation.

### **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011 FOLLOW UP MISSION**

- (1) **BASIS:** Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety.  
*Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective*

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011 FOLLOW UP MISSION

*coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.*

*2.18. 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:*

*(1) Safety of workers and the public;*

*(3) Applications of radiation in medicine, industry and research;*

**GPF2** **Good practice:** The Framework co-operation agreement between the Ministry for Health and the CSN signed in 2010 is an important initiative to coordinate national efforts on radiation protection.

## 5. SAFETY AND SECURITY OF RADIOACTIVE SOURCES

### 5.2 NATIONAL REGISTER/INVENTORY

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

S16 **Suggestion:** CSN should establish a formal mechanism for exchange of information with the Customs about notification that a radioactive source has actually entered or left the country to make it fully traceable.

#### Findings from the 2011 Follow-Up Mission

**Suggestion S16:** CSN has in dialogue with the Customs chosen to prioritize the illicit traffic of radioactive materials, in order to meet the MEGAPORT initiative launched by the US. The *Action Protocol in case of detection of inadvertent or illicit traffic of radioactive materials through Spanish Sea Ports of general interest* was brought to force in June 2010. This agreement involves all interested parties and regulates the responsibilities and actions:

- CSN
- State Agency for Tax Administration (AEAT) who operates three systems of gate detectors currently in use (three more in pipeline), and notify any detection to the CSN.
- The Ministry of internal affairs (MIR) which organize the police departments/security actions/information policy
- The ministry of public work (MF) which includes the Customs who buy and install the gate detectors. The private radiation protection services licensed by the CSN give advice to the Customs, carry out the calibration and giving service to the equipment.
- The Ministry of Industry, tourism and trade (MITYC) is the coordinator of the action plan; they also authorize legal storages of radioactive material in Spain. When an illicit source is found, a special authorization is issued.
- ENRESA manage legal radioactive waste in Spain.

When it comes to legal trade of radioactive sources a formal agreement for co-operation between CSN and AEAT is under development. There is been launched a new working group for formal cooperation, one meeting has already been arranged, and an agreement between the Greek authorities is being used as reference and starting point for the discussions.

In the Annex to the Code of Conduct IAEA has given guidance to the Import and Export of Radioactive sources (May 2009). CSN has provided a national contact point to an international list of similar contact points. Within European Union the exchange of information about sources is regulated in EURATOM 1493/1993. Legal trade of radioactive sources between Spain and countries outside EU, is regulated by this new annex to Code of Conduct. The review team was introduced to how this was working for Category 1 and 2 sealed sources respectively. If a Category 1 source is imported for example from Canada, the CSN contact point will get a request for signed consent from the Canadian contact point. CSN will verify that the Spanish facility has the necessary licenses, and give that consent. This will include a form with information from the exporting state about the source and from the importing state about conditions of the consent. Forms about the transfer include all details about the shipment, and there is a separate Export notification form. After the Category 1 source has arrived in the facility, they will notify CSN of the transfer, and the source will be included in the CSN source register.

The communication about legal sources goes directly between national contact points and the facilities. The Customs are not notified in beforehand, they just handle the situation according to their routines when the source arrives. The Customs has expressed the opinion to CSN that the safety and security issues are satisfactory without this additional notification. In addition, the CSN inform there is a very good informal collaboration between them and the Customs, and thinks the system functioning well. A certain incidence about suspected contaminated steel from India/China was discussed with the team to illustrate this. It is also referred to the actions through many years of CSN in the control and detection of orphan sources (The Spanish Protocol for Collaboration on Monitoring Radiation of Metallic Materials Monitoring). This protocol has been used as reference in the development of a international guide for radiological control in steel factories (revision of DPP of DS 411).

The Action Protocol in case of detection of inadvertent or illicit traffic of radioactive materials through Spanish Sea Ports of general interest brought to force in June 2010 involves all relevant parties in Spain and clarifies the responsibilities and actions in cases when illicit radioactive materials are detected. This effort is acknowledged as the most important formal mechanism for exchange of information about traffic of radioactive materials though Spain.

**Suggestion 16 (S16): is closed.**

### **New findings from the 2011 Mission**

There were no new findings in the 2011 IRRS Follow up Mission.

## 6. TRANSPORT OF RADIOACTIVE MATERIAL

### 6.3.ORGANISATION OF THE REGULATORY BODY

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

S17 **Suggestion:** To support the work of the Committee for the Coordination of the transport of dangerous goods of the Ministry of Public Works, Memoranda of Understanding or equivalent should be established where possible, with the other competent authorities with competences in the inspection of dangerous goods.

#### Findings from the 2011 Follow-Up Mission

**Suggestion S17:** The review team was given some brief background information about the situation in Spain. The Ministry of public work (MF) is in charge of all transport and inspections of dangerous goods. The Ministry of internal affairs (MIR) organizes the police departments; they are issuing the licences to the drivers of dangerous goods. CSN have requirements to the content of the training with respect to radioactive transports. CSN inspect at start and endpoint of the transport, packages and offices. They check labelling of package/vehicle, package design/ state of package, training licence of the driver, monitor radiation on surface of the package/surface of vehicle/contamination, etc. They priorities the inspections according to the risk philosophy, i.e. from the 60 – 70 annual inspections on transport 20% are devoted to fissile material and type B sources, while 80% are devoted to type A radiopharmaceuticals. The police inspect dangerous goods during more general inspections on road, and obviously all would benefit from collaboration about inspection content and routines.

The review team was introduced to a translation of the draft protocol for the collaboration agreement between the Ministry of public work (MF) and the CSN on the actions for surveillance and control in the field of transport of radioactive material. There has been several meetings between the technical staff in MF and CSN about this issue, the text has been reviewed in the respective legal departments; the agreement only remains to be accepted formally in the CSN and MF and then to be signed.

This protocol constitutes a necessary framework and the first step for the development of more specific technical procedures on the three different transport areas (see, land, air).

**Suggestion 17 (S17) is closed.**

#### New findings from the 2011 Mission

There were no new findings in the 2011 IRRS Follow up Mission.

## 7. EMERGENCY PREPAREDNESS

### 7.4. EXERCISES

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

- S18 **Suggestion:** CSN should upgrade guidance on radiological emergencies to support use of the IAEA threat assessment categories.
- S19 **Suggestion:** CSN should continue developing planning for *the actions to be taken after an emergency*, taking into account the specific national conditions and international recommendations.
- S20 **Suggestion:** CSN should consider extending the existing national guidance for emergency (group one) workers by introducing a more selective specification of conditions based on IAEA EPR-method-2003 -.

#### Findings from the 2011 Follow-Up Mission

**Suggestion 18:** After lengthy discussions and negotiation with other agencies, the Government approved a new Basic Directive for Radiological Emergencies (DBRR) in November 2010. This new Basic Directive complements the existing Basic Plan for Nuclear Emergencies and the Basic Directive for Transport Emergencies. The DBRR, which applies to radiological emergencies other than in NPPs or in transport, sets out the high level criteria to be applied in more detailed national and regional planning. It establishes emergency and recovery phases of an incident and sets out the criteria for emergency planning zones. The DBRR incorporates directly the ‘threat assessment categories’ defined in the IAEA GS-R-2 safety requirement.

The CSN will be closely involved in implementation of the DBRR. It must prepare a radioactive sources inventory and technical guidance for emergency actions and responder protection etc. The CSN will also review and report on the National Plan for Radiological Emergencies being developed by the Ministry of Interior and regional government emergency plans (and it has already done so for one region).

The intent of the Suggestion has been very well met.

#### **Suggestion 18 (S18) is closed.**

**Suggestion 19:** CSN has been participating through contracts with technical support organizations in the development of a European decision-making tool for application in planning actions to be taken after an emergency. The tool (RODOS) has been installed in the CSN’s emergency centre and the task of populating it with data from relevant Spanish sites has begun. It is taking part in the further European development of the tool.

Since the 2008 mission, CSN led Spanish agencies in participation in international nuclear emergency exercises such as IAEA’s ConvEx-3, and NEA’s INEX 4 exercises. This last exercise was a table-top exercise focusing on arrangements for, and issues in, consequence management and transition to recovery in response to a malicious act involving a radiological dispersion device in an urban environment. At the instigation of CSN, the Spanish exercise also included a field exercise.

CSN plans to review and implement findings from the INEX 4 exercise and further develop technical guidance relevant to the recovery phase.

These actions show that CSN is very active in working on planning for actions to be taken in the recovery phase of an emergency. Its activities are entirely consistent with Suggestion 19.

#### **Suggestion 19 (S19): is closed.**

**Suggestion 20:** The CSN is in process of developing two procedures: PT.VI.28 Dosimetry in Nuclear Emergencies and PT.VI.29 Dosimetry System in Radiological Emergencies. These draft Procedures are currently being finalized within CSN and CSN staff expect to complete them by mid 2011. The Procedures apply the overall guidance dose for emergency workers involved in urgent and important actions (potentially life-saving) based upon the recommendation in GS-R-2. They also set out control steps for decision-making in relation to workers who may be exposed to these doses.

The CSN is in the process of implementing the suggestion through development of the Procedures referred to above.

**Suggestion 20 (S20): is closed on the basis of progress and confidence.**

### **New findings from the 2011 Mission**

The basic INEX 4 exercise is only a table top activity. The CSN in cooperation with other relevant agencies organized a field exercise as a part of their INEX 4 exercise.

### **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011 FOLLOW UP MISSION**

**BASIS:** GSR Part 1 Requirement 8: The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency.

Para 2.22 'Such preparations shall include planning the actions to be taken both in an emergency and in its aftermath.

GPF3 **Good Practice:** The CSN's successful carrying out of a field exercise with other relevant agencies as a part of the table-top INEX 4 exercise on radiological emergency consequence management.

## 8. INFRASTRUCTURE FOR RADWASTE, DECOMMISSIONING AND REMEDIATION AND ENVIRONMENTAL SURVEILLANCE

### 8.2.3. Waste streams covered by the PGRR

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

- S21 **Suggestion:** CSN should work towards, and the Government should consider, adjusting the procedure for approval of the General Radioactive Waste Plan, or PGRR, so that the plan is submitted to the Ministry of Industry, Tourism and Commerce (MITYC), together with a technical review of the safety- and radiation protection- related matters of the same document by the CSN, to assist the Ministry in judging the technical considerations underpinning the strategy laid out in the PGRR.
- S22 **Suggestion:** The CSN should work with the Competent Authorities to regulate the establishment and maintenance of a national centralised inventory of existing and anticipated radwaste, including also waste that could be generated outside regulated facilities.

#### Findings from the 2011 Follow-Up Mission

**Suggestion 21:** The main strategic document in radioactive waste management, including spent fuel management, is the General Radioactive Waste Plan or PGRR<sup>1</sup>. The Plan considers the generation of radioactive waste, the courses of action, and the economic and financial aspects. The current PGRR is the sixth, approved by the Cabinet of Ministers on 23 June 2006. The approval of the 7th PGRR is currently pending, as further discussed below. The legislation prescribes the development of the PGRR by the National Waste Management Company, ENRESA<sup>2</sup>, every four years. The plan needs to be endorsed by the Ministerio de Industria, Turismo y Comercio (MITYC) before final approval by the Cabinet of Ministers.

An estimate of the waste inventory is included in the PGRR, based on a scheme for waste classification and through analysis of a number of waste streams, including spent fuel, as laid out in the report of the 2008 Mission.

Suggestion 21 deals with the approval process for the PGRR. The 2008 Mission identified that the review of the PGRR by CSN occurred at a late stage of the approval process, and the 2008 Mission was of the view that MITYC's handling of PGRR needed to be informed by CSN at an early stage.

The issue has been addressed in Law 11/2009<sup>3</sup>, which has introduced a modification to Law 25/1964, on Nuclear Energy, regulating CSN's competence for issuing a mandatory report in the General Radioactive Waste Plan approval process. Law 11/2009 states:

*“The Government shall be responsible for establishing policy regarding radioactive waste management, including spent nuclear fuel, and the dismantling and decommissioning of nuclear facilities, through the approval of the General Radioactive Waste Plan, which shall be submitted to it by the Ministry of Industry, Tourism and Trade following a report by the Nuclear Safety Council and after having heard the Autonomous Communities in relation to land planning and the environment, and shall subsequently notify the Parliament in this respect.”*

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<sup>1</sup> Plan General de Residuos Radioactivos

<sup>2</sup> Empresa Nacional de Residuos Radioactivos, SA

<sup>3</sup> Law 11/2009, of October 26<sup>th</sup>, Regulating Limited Investment Companies Quoted on the Real Estate Market

In further exploring the development of the PGRR, the Follow-up Mission noted that the development and approval process relevant to the seventh plan is currently put on hold. While ENRESA has submitted the new PGRR in accordance with its obligations, the Government has requested that the outcome of the site selection process for the Central Storage Facility for spent nuclear fuel and high-level waste (covered in more detail below) shall be incorporated in the 7th plan, which also means that the plan may have to be modified to take into account the consequences of this outcome. It is currently not known when the approval process can resume and what the consequences might be for the draft PGRR. It is noteworthy that the draft 7th PGRR has not yet been officially submitted to CSN for review, although ENRESA has provided CSN with a copy. Pending the further processing and eventual approval of the 7th PGRR, the 6th PGRR remains the main planning document, except for the financial provisions where changes have already been implemented.

The Follow-Up Mission concludes that the modification to Law 25/1964 introduced through Law 11/2009, has adequately addressed the concerns raised in Suggestion 21. However, the Mission notes that there is currently a halt in the approval process of the 7<sup>th</sup> PGRR and hopes the review process will resume shortly.

#### **Suggestion 21 (S21): is closed.**

**Suggestion 22:** This suggestion concerns the waste inventory. The waste streams, as discussed in the PGRR, are generally well characterised and licensees are required to maintain records of each waste package generated and stored in the facility, containing the relevant information associated to the waste. Reporting to the regulatory authorities of quantities and types of waste generated in the nuclear and radiation facilities is mandatory. In the NORM area, substantial activity has in recent years gone into the characterisation of sources, and pathways of exposure, to natural radiation. CSN has surveyed a variety of environments and activities in which health concern may arise. Out of a substantial list of surveyed environments/activities, a few emerge as requiring additional attention, inter alia the ceramic industry, fertilizer industry, use of thorium in welding, and carbon combustion.

The 2008 Mission identified that there are no legal provisions for a centralized national waste inventory including existing and anticipated waste. The 2008 Mission suggested that CSN should work with relevant authorities to regulate the establishment and maintenance of a national register, including such waste (e.g. NORM) that may be generated in non-regulated facilities and activities.

Shortly after the 2008 mission, collaboration was established between CSN, ENRESA and MITYC to address the issue of regulation and improvement of the national inventory, with particular reference to NORM waste. Terms of Reference have been drawn up and activities and reporting are ongoing. The forum combines the three parties that are responsible for policy, management and regulatory oversight.

The Follow-up Mission concludes that activities to further identify and characterise waste categories give satisfactory reassurance that Suggestion 22 can be closed.

#### **Suggestion 22 (S22): is closed on the basis of progress and confidence.**

### **New findings from the 2011 Mission**

There were no new findings in the 2011 IRRS Follow up Mission.

#### 8.4. THE SYSTEM FOR MANAGEMENT OF SPENT FUEL AND HIGH-LEVEL WASTE

##### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

- R3 Recommendation:** CSN should work with other competent authorities to encourage the development and communication of plans for final disposal of spent fuel and HLW, and contribute to setting the appropriate targets and conditions that would, from all points of view, govern the process, so that there is no unnecessary delay in the solution of the problem, and that also gradually would improve the estimates of future costs for the final radwaste management.

##### Findings from the 2011 Follow-Up mission

The 2008 Mission Team identified that spent fuel management in Spain, as well as management of some other high-level waste (HLW), is constrained by the absence of a final solution for the disposal of the spent fuel and waste, as well as by the absence of a central interim storage facility for such wastes. This has had consequences for the current storage strategies for spent fuel; saturation of the reactor storage pool has occurred at the Trillo NPP, leading to a modification of the plant to include a facility for dry storage. Similar solutions are under way for Ascó, and have been applied for José Cabrera as a consequence of the decommissioning of the facility. Furthermore, there is no storage facility that can accept the reprocessing waste originating from Vandellós 1, currently stored in France, that originally was planned to be returned in 2010. In the interim, pending the operation of a storage facility in Spain for this purpose, reprocessing waste is still stored in France.

##### *Progress regarding centralised storage of spent fuel and high level waste*

It was originally intended to have a Centralised Temporary Storage (CTS) facility in operation in 2010, to accommodate for the return from France of the reprocessing waste from Vandellós 1. The conceptual design of the CTS, as already on a provisional – but binding – basis is endorsed by the CSN, is relatively simple and in most regards passive. The reference facility for the CTS is the Habog facility in The Netherlands. A technology centre is planned to be co-located with the CTS. The main objective of the technology centre is to ensure the availability of technologies and know-how required for the final management of spent fuel and high-level waste, through the performance of the research and development plan<sup>4</sup> and by providing support to other ENRESA activities and facilities.

While the original planning target for the CTS has not been met, the Follow-Up Mission notes substantial progress since the 2008 Mission. The Royal Decree 775/2006, dated 23<sup>rd</sup> June, created the Interministerial Committee for the establishment of the criteria that must be met by the site for the CTS and its associated technology centre, and for drafting a report on possible sites, for submission to the Government. The Interministerial Committee is comprised of members from six Ministries plus one member from the Cabinet of the Prime Minister; it is chaired by MITYC through the Secretary of State for Energy, whereas the vice-chair is the representative of the Ministry of the Environment.

The Interministerial Committee is advised by a Technical Advisory Committee, with recognized academic and technical competence, that will assist the Interministerial Committee in discharging its duties, those being: to establish technical, environmental and socio-economic criteria to be fulfilled by candidate sites; to promote public communication; to develop relevant procedures; and, to propose suitable candidates for siting the CTS and the technical centre based on its evaluation of their suitability to host the facilities.

<sup>4</sup> The current plan, Plan de I + D, developed by ENRESA and published in 2009 as Publicación Técnica 06-2009, covers the years 2009 - 2013

In December 2009, the Secretary of State for Energy launched a public call for candidate municipalities to host the CTS<sup>5</sup>. The call was preceded by an initial screening, indicating areas that were unsuitable for the CTS. Fourteen municipalities responded to the call; of these, five were rejected for administrative and/or procedural reasons. One candidate municipality was screened out as the siting of the CTS within the municipality would impact on areas identified for the purpose of nature conservation. The eight remaining candidate municipalities, in five regions, are: Congosto de Valdivia, Melgar de Arriba and Santervas de Campos (Region of Castilla - Leon); Albalá (Extremadura); Yebra and Villar de Cañas (Castilla - La Mancha); Zarra (Valencia); and, Ascó (Cataluña). Most of these municipalities have currently no involvement with nuclear activities.

Considering the call was open for just one month, the fact that 14 municipalities expressed interest in the CTS must be considered a good turnout. The municipalities are small; the fact that 300 workers would be engaged in construction and that the maintenance and operation of the CTS and the technical centre would offer long-term work opportunities, as well as opportunities for local infrastructure development, has probably had a significant attraction value. Even if only a fraction of the workforce would be recruited locally, undoubtedly the incentive is strong for very small and possibly stagnant municipalities to host the CTS and the technical centre. A further economic incentive comes from the fact that ENRESA, by Order<sup>6</sup>, is authorized to allocate funds to Councils in whose territory facilities for temporary storage of spent fuel and high-level waste will be sited. The Order is currently being revised and updated.

In volunteering as candidate in response to the aforementioned call, a municipality has committed to: make the land available that is required for the facility; grant the necessary licenses within its jurisdiction that are necessary for the conduct of the project; provide necessary arrangements to facilitate the project; and, participate in the process until the Government has made its decision, after which only the selected municipality will continue its involvement with the Government. The picture is made somewhat complicated by the fact that the Region may not always be supportive of a municipality's decision to volunteer. Whilst the Region cannot overturn a municipality's decision to participate in the project, the Government's ambition would normally be to have the support of the Region in the selection of a site.

The process of drawing up the final list of municipalities involved substantial communication and public participation. Furthermore, more than 14 000 submissions were received that were critical of the plans, many of them with identical content. Documentation and plans can be accessed from a dedicated website, [www.emplazamientoatc.es](http://www.emplazamientoatc.es).

The Interministerial Committee submitted its evaluation to the Government in September 2010. The decision and announcement of the selected municipality is still pending at the time of the Follow-up Mission.

Upon selection of the site, ENRESA will submit an application to site and construct the facility. The time required for submitting the application would normally be in the order of 15 months. CSN's review of the application will be facilitated by the fact that a generic design approval already was given in 2006, and that CSN staff are familiar with the concept. The process is further facilitated by the publication in 2010 of CSN's safety criteria<sup>7</sup> that are applicable to CTS and that will guide ENRESA in the preparation of the application. Thus, the time required to review the application, provided it is complete and gives enough reassurance of the safety of the facility, may

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<sup>5</sup> Resolution of December 23<sup>rd</sup> 2009 by the Secretary of State for Energy initiating the process of of public proposals for the selection of candidate municipalities to house the site of the Centralised Storage (CTS) facility for spent nuclear fuel and high level radioactive waste and associated technology centre.

<sup>6</sup> Order of 13<sup>th</sup> July 1998 amending Order of 20<sup>th</sup> December 1994, developing Royal Decree 1522/1984 of 14<sup>th</sup> July, as authorising the constitution of the "Empresa Nacional de Residuos Radioactivos, Sociedad Anónima (ENRESA)

<sup>7</sup> Instrucción IS-29, sobre instalaciones de almacenamiento temporal de combustible gastado y residuos radioactivos de alta actividad

be comparatively short. Following a favorable review by CSN, and provided the Ministry of the Environment has approved the Environmental Impact Statement, the matter can be referred to MITYC for decision.

Realistically, the period for establishing a facility with the first four storage vaults completed would be around six years from the decision and announcement by the Government. In a second step (totaling six years) another four vaults will be added; in step three, finishing 14 years after the operations started, another four vaults are planned to be ready.

The Parliament has recently (December 2010) requested CSN to, within six months, submit a report to the Parliament on the regulatory process being adopted for the CTS.

#### *Progress regarding spent fuel and HLW disposal*

With regard to a *disposal* facility for spent fuel and HLW, the situation at the time of the Follow-up Mission is essentially the same as it was at the time of the 2008 Mission. The plans foreshadow construction of a deep geological disposal facility in clay or granite, 600 m or more below the surface, with horizontal emplacement of canisters in disposal tunnels. The target year starting operations is 2050. The year 2050 mainly serves as a reference point in time for the purpose of ensuring that enough funds will be available to cover the costs associated with disposal. No siting process is currently ongoing.

However, in accordance with the 6<sup>th</sup> PGRR, ENRESA has conducted a number of studies, including analysis of management options, feasibility studies of new technologies, generic design studies, and review of decision making processes as developed and applied internationally. ENRESA is currently focusing on maintaining its capabilities and competence, through mainly desk-top studies and through following the development internationally in the managerial, technical and decision making areas. Spain, through the different organisations involved in waste management, is also an active participant in the definition of reference levels within WENRA and in the development of a waste management Directive within EURATOM.

### **Recommendation 3 (R3): is amended.**

#### **New findings from the 2011 Mission**

The Follow-Up Mission notes that no major progress has been made since the 2008 Mission with regard to a disposal facility for spent fuel and high level waste. The plans, as laid out in the 6<sup>th</sup> PGRR, are still valid and current actions are more focused on maintaining competence and keeping up-to-date with the international developments, rather than advancing the Spanish programme *per se*.

However, substantial progress has been made regarding the plans to establish a CTS and its associated technical centre, in accordance with the PGRR. The process has been transparent and consultative, mechanisms for decision making clearly established, and relevant criteria defined and communicated. Notwithstanding the fact that the decision of the site by Government is still pending and that CSN yet has to perform its formal review of the application once it has been presented by ENRESA, the Team concludes that the process has been in accordance with best international practice. The Team is also of the view that the experience from the CTS siting will be an important experience that will inform and assist in implementation of subsequent stages of the disposal programme, as laid out in the PGRR. The Follow-Up Mission considers the siting process as good practice for a nuclear installation of this kind.

Considering that many issues covered by Recommendation 3 are outstanding, the Follow-Up Mission concludes that Recommendation 3 cannot be closed. However, the Follow-Up Mission also acknowledges that substantial progress has been made in some areas covered by the Recommendation. In recognition of that progress, Recommendation 3 has thus been amended, as set out below.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011 FOLLOW UP MISSION

**BASIS:** GSR Part 1, Requirement 10: *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 the 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 shall enforce continuity of responsibility between successive authorized parties.*

2.30. *Radioactive waste generated in facilities and activities shall be managed in an integrated, systematic manner up to its disposal. The interdependences of the steps in the entire management process for radioactive waste, and likewise for spent fuel, shall be recognized [3].*

GPF4 **Good practice:** The arrangements for a transparent and technically sound siting process for the Central Temporary Storage (CTS) facility and its associated technical centre is good practice

RF1 **Recommendation:** CSN should continue to work with relevant competent authorities and other bodies to facilitate the process for siting a disposal facility for spent fuel and high level waste, as laid out in the 6<sup>th</sup> PGRR and as approved by the Government. CSN should take the experiences from the siting of the CTS facility into account and contribute to the development of the regulatory framework, including siting criteria, technical criteria as necessary according to international developments and requirements, consultative mechanisms, and information, that would guide ENRESA in the development of future General Waste Management Plans, and facilitate the development of a conceptual design as well as the initiation of the siting process.

## 9. MANAGEMENT SYSTEM

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2008 MISSION

- R4 **Recommendation:** CSN should formalise and implement an internal audit programme of the management processes. The programme should ensure that all processes are audited within a defined time period. To support this programme a number of internal auditors should be selected among the staff and given adequate training. In connection with the audit programme, a systematic approach to the management of non-conformances of processes and products should be developed and formalised.
- R5 **Recommendation:** CSN should develop a methodology and implement management system reviews to be conducted at planned intervals by internal or/and external resources. This programme should ensure the continuing suitability and effectiveness of the management system as a whole and its ability to enable the objectives of the organisation to be accomplished.
- S23 **Suggestion:** CSN should insert into the management system manual a more concise organizational policy statement which gives a clear message from the Council to stakeholders about what they can expect the CSN to deliver.
- S24 **Suggestion:** To support management self-assessments, CSN should perform assessments (surveys) of the regulatory (safety) culture among all staff at planned intervals and develop a mechanism to feedback and act on the results. These surveys could be included in the planned working climate surveys.
- S25 **Suggestion:** CSN should implement an up to date software application on the intranet of the process map and make it possible to open all attached documents from the map.
- S26 **Suggestion:** CSN should implement a mechanism to identify opportunities for improvement of the management system as well as to monitor improvement actions and check the effectiveness of the improvements. An instrument for this could be mailboxes on the intranet, attached to each management system process, for collecting comments and suggestions from the staff.
- S27 **Suggestion:** CSN should develop a procedure to manage and assess its organisational change.

### Findings from the 2011 Follow-Up Mission

**Recommendation 4 (R4): Audit process and its implementation:** CSN revised its Management System Manual and its second revision was approved on 15 December 2010. The document is available on CSN Intranet. The Management System Manual indicates, in section 6.3.2, that internal audits will be performed based on the basic audit plan and references the procedure for internal audit PA.XI.01, which was issued on 19 Feb 2009. The audit procedure is based on ISO approach and it is, in general, consistent with the requirements of GS-R-3.

It was noted that Appendix VII, Process Descriptions, of the Management System Manual, include Management System in the list of processes, but process descriptions related to the management system areas are not included. For example, there are no process descriptions in the Management System Manual addressing measurement, assessment and improvement, including self-assessment, independent assessment, management system review, non-conformances, corrective and preventive actions and improvement. Meanwhile, references are made to procedures supporting some of those processes.

CSN internal audit process is implemented based on a basic audit programme/ plan, which ensures that every process (strategic, operational, and support) is audited on a regular basis, which varies from 2 to 4 years. The basic audit plan is included as Annex IV of the Management System Manual and, based on it, annual plans are developed by the Planning, Assessment and Quality Unit (UPEC) in consultation with the inspection office; the annual plan is approved by the Management Committee and included in CSN annual work plan

The CSN internal audit process was not included yet in the basic and / or annual audit plan and this issue will have to be further discussed and a decision has to be taken on how to address this issue in the near future. It was noted that, in the Management System Review Report, from 15 Nov 2010, the issue of external audits was also discussed and an action was raised for follow-up. UPEC was requested to prepare a proposal for Management Committee's discussion and decision

The implementation of the internal audit processes started in 2009 and during 2009 and 2010 a number of 17 audits, addressing 14 processes, were conducted. For each process (e.g. transport) involving participation of regional authorities, two audits are conducted, one related to CSN activities and another one addressing the activities performed by the regional authorities.

The internal audit process for CSN activities is managed by UPEC. The audit process that includes audits of activities performed by the regional authorities is also managed by UPEC, and it is conducted with the participation of the CSN Inspection Office.

A number of 40 CSN staff members were trained as internal auditors, through a three-day course, which was developed specifically for CSN. Three lead auditors were selected from those staff members, taking into consideration their previous experience in conducting quality assurance/ management audits.

IRRS team discussed with two of the lead auditors about the implementation of the process and advantages for the organization. The lead auditors were of the opinion that the process is working well, it was accepted by the organization and there are major benefits in identifying opportunities for streamlining the existing processes.

The IRRS team reviewed the documentation of two audits conducted in 2010 related to CSN activities for Services Entities, Radiological Surveillance and Control of the Workers and one related to the Assessment Process for Nuclear Installations (Evaluación II NN y del Ciclo). It was noted that the documents were in compliance with the audit procedure PA.XI.01, revision 1. The Audit reports raised a number of non-conformances and identified several opportunities for improvement. The internal audits reports are available on CSN Intranet.

### **Non-conformances, opportunities for improvement and their treatment**

The Management System Manual indicates, in section 6.6, in general terms, how non-conformances are identified, controlled and reported. Section 6.7 of the manual describes how opportunities for improvement of the management system are identified and addressed. These chapters of the manual do not reference any supporting procedure, but the procedure for internal audit PA.XI.01, revision 1(19 Feb. 2009) addresses these issues. It is suggested to consider including the appropriate reference to procedure during the next revision of the manual.

The internal audit procedure defines non-conformances as a non-compliance with a requirement. In order to allow for effective identification of non-conformances by staff it is necessary to ensure that the organizational outputs and the associated requirements are well understood. While the section 5.3.2 of the management system manual indicates that CSN products are contained in documents, neither the manual or the internal audit procedures describes the products of the regulatory activities. It is suggested to consider developing a list of products (e.g. licence, assessment report, inspection report, regulatory documents, etc) and include it in the management system manual and its supporting documents, in order to facilitate identification of non-conforming product and processes and to encourage individuals to apply the non-conformance process.

Based on the audit procedure, the non-conformances are classified in three categories (A, B and C), based on their perceived importance for safety. The classification of non-conformances is conducted by UPEC, not by the lead auditor. There are no detailed instructions on how the safety impact of a non-conformance should be assessed. In addition, section 5.7 of the same procedure indicates that the causes of the non-conformances will be analysed and identified, but there are no further instructions on how to determine the associated causes, generic (common) issues and repeat occurrences. It is suggested to consider these issues during the further improvements of the internal audit process.

The main source for identification of non-conformances are the internal audits. In addition, non-conformances may be generated as a result of suggestions for improvement made by CSN employees, as described in the section of the report addressing the Suggestion 26 (S26). It was noted that 74 non-conformances were raised as a results of the audits conducted in 2009 and 2010. All of them are of category “C” (no safety significance).

The audit procedure contains a template for initiating a non-conformance. In addition, the procedure allows for identification of “proposals for improvement”, which could be also included in the audit report. While non-conformances are collected, analysed and their status reported to Management System Committee, it was noted that the proposals for improvement, documented in the audit reports, are not currently managed in the same way. The IRRS team was informed that they will be analysed and processed in a similar way after the first audit that will take place in 2011. This is also reflected in the decision of the Management System Review from 15 November 2010.

#### **Recommendation 4 (R4): is closed.**

**Recommendation (R5):** The Management System Manual contains, in section 6.5 and Annex V, generic information on the Management System Review.

The first Management System Review took place on 15 November 2010, with the participation of the members of the Management System Committee. IRRS team was presented with a copy of the meeting notes. Annex 2 of the document contains the history of the actions taken by the Committee from Feb to Nov 2010 related to the review of the CSN management system. Annex 3 of the document includes information on the elements included in the analysis of the suitability and effectiveness of the management system and identifies the necessary actions to be taken. This information constitutes a good basis for development of a process description and a supporting procedure for conduct of Management System Reviews. It is suggested to developed these documents and include and reference them in the Management System Manual.

CSN decided that the Management System Review will take place two times per year and additional reviews can be initiated by the Management System Committee, as needed.

#### **Recommendation 5 (R5): is closed, based on progress and confidence.**

**Suggestion 23 (S23):** The CSN organizational policies of CSN, contained in the revision 1 of the Management System Manual were discussed by the Management System Committee, which took place on 14 September 2010. Benchmarking was conducted with other regulatory bodies (e.g. STUK) and, as a result of the discussions and analysis, a revised set of policies, which also includes security aspects, was developed. CSN believes that the revised document meets their organizational needs, ensures consistency and eliminates duplication. IRRS team concurs with this position.

#### **Suggestion 23 (S23): is closed.**

**Suggestion 24 (S24):** The CSN draft work plan for 2011 (CSN/ Plan/ 10/05), contains a planned assessment of the safety culture of regulatory body’s staff.

The methodology and process for conducting such an assessment had not been yet defined and resources have not been allocated. The IRRS team was informed that, in addition to its internal resources CSN is considering to engage external experts in this area.

**Suggestion 24 (S24): is Open.**

**Suggestion 25 (S25):** A feasibility study for developing a software application (MAPA) for facilitating the access, via intranet, to the processes and supporting documents related to the management system, was conducted in 2009. The development of the software started in the first quarter of 2010 and currently the tool is in testing mode. It is expected that MAPA will be fully operational by April 2011.

A demonstration of the tool was provided to the IRRS team. It was noted that MAPA allows for inclusion of all three types of processes described in the management system manual and will contain all supporting procedures. Each process contains the list of its procedures supporting and the software has search capabilities, based on several criteria, so the users should be able to access the necessary procedures in an easy way. The MAPA software will not contain a dedicated module for accessing various forms (e.g. inspection reports, templates for the review and assessment reports, initiation of changes to procedures, non-conformances, etc.) to be used for conducting regulatory activities, but the tool has the capability of adding documents, as necessary. Currently, the initiations of changes to procedures are done via a different system, using also the intranet, but, it is envisaged that, in the future, the management of procedural changes will be done using MAPA. In addition, MAPA is designed for allowing the preparation of audit reports on-line, including the initiation of non-conformances and opportunities for improvement.

**Suggestion 25 (S25): is closed, based on progress and confidence.**

**Suggestion 26 (S26):** The implementation of actions necessary to implement Suggestion 26 was initiated through a note (18 Feb. 2009) from the Secretary General, which indicated that a pilot will be conducted for collecting CSN staff's suggestions and comments related to CSN Management System, via a "mail-box". The note describes the main characteristics and steps of the process to be applied. And it indicates also that, based on the experience gained during the pilot, a procedure will be developed.

The tool was developed and it became operational in February 2009. The initial technical problems, related to the accessibility of the tool, were corrected and the tool is currently used by CSN staff.

A demonstration (of the tool developed for collecting CSN staff's suggestions and comments related to CSN Management System) was provided to the IRRS team. Based on the demonstration and the discussion with the counterparts it was noted that the development of the tool was done in accordance with General Secretary's note and responsibilities were assigned for implementation of various process steps.

The IRRS Team noted that staff members do not have access to see the non-conformances raised as a result of their suggestions, but it was informed that MAPA will address this issue.

To-date seven suggestions were received, related to methodology for internal comments for procedures, internal audit procedure, availability of licensees' documents, etc. The IRRS team reviewed the actions taken in response of one suggestion, related to the availability of licensees' documents (technical specifications) and it was noted that the process steps were followed.

Section 6.7, "Improvement" of the Management System Manual does not contain information on the CSN process implemented, as described above, for collecting CSN staff's suggestions and comments related to CSN Management System. This process should be regarded as one of the major inputs for initiating improvements of the management system and a process description should be included in the management system manual and a procedure should be developed and referenced, as indicate in the note from the Secretary General.. This suggestion should be

considered in conjunction with the similar comments regarding inclusion of process descriptions for measurement, assessment and improvement, which were done for the Recommendation 4.

**Suggestion 26 (S26): is closed, based on progress and confidence.**

**Suggestion 27 (S27):** The Management System Manual contains, in section 5.3.6 “Change Management in the Organization” some information on the main steps taken by CSN for conducting organizational changes. No process description and/or procedure addressing the management of organizational changes are included or referenced in the manual.

Based on the discussions with the counterparts and the review of relevant information, IRRS team noted that CSN Management Committee analyzed various documents (e.g., issued by IAEA, CSNI, etc) on the topic of management of organizational changes. For example, CSN conducted a comparison of the process steps documented in IAEA TECDOC 1226, Managing Change in Nuclear Utilities and those currently conducted by CSN. The result shows that CSN conducts eight steps from 24 described in the TECDOC. The analysis also concluded that the documents considered were developed for utilities and no guidance for the management of organizational changes is available for regulatory body.

IAEA safety standard GS-G-3.1, Application of the Management System for Facilities and Activities provides guidance in support of IAEA safety requirements GS-R-3, The Management System for Facilities and Activities, and both documents are applicable for the regulation of nuclear facilities and activities. GS-G-3.1 contains specific guidance for managing organizational changes, including their classification, analysis and assessment, review, control of impact of changes, etc.. Management of organizational changes is a generic management system process, as defined in GS-R-3, and it should be described and documented in an adequate way. IRRS team suggests that the information contained in the CSN Management System Manual be further developed and a process description and procedure be developed and referenced in order to ensure consistency in assessing, implementing and monitoring of organizational changes.

**Suggestion 27(S27): is open.**

**New findings from the 2011 Mission**

IRRS team noted that CSN has developed and implemented an internal audit process in a relative short period of time and was successful in training a considerable number of staff as auditors and lead auditors. The process is strongly supported by the Management Committee and was adopted by CSN staff. The participation of auditors from various organizational units allows for facilitating the exchange of information and regulatory practices applied to the regulation of nuclear facilities and activities. The audit process is effective in identifying non-conformances and opportunities for improvements and tracking them until completion of necessary corrective actions.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011 FOLLOW UP MISSION**

**BASIS:** GS-R-3 §6.3 states that *“Independent assessments shall be conducted regularly on behalf of senior management:*

- To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives;*
- To determine the adequacy of work performance and leadership;*
- To evaluate the organization’s safety culture;*
- To monitor product quality;*
- To identify opportunities for improvement.”*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011  
FOLLOW UP MISSION**

**GPF5 Good Practice:** The internal audit process developed by CSN, with strong support from the senior management and staff participation, was implemented in a timely manner and allows the organization to assess the effectiveness of its regulatory processes and to identify opportunities for improvement.

## 10. PHYSICAL PROTECTION IN NUCLEAR INSTALLATIONS

As part of the Follow-up Mission a team member reviewed the efforts of CSN to address the recommendations and suggestions from the 2008 Mission. CSN has made considerable progress in addressing these recommendations and suggestions, with all but one of them being evaluated as closed or closed based on progress and confidence. This is especially noteworthy given the complexity and sensitivity of many of the issues and the number of national organizations having roles and responsibilities associated with physical security of nuclear facilities, nuclear materials and radioactive sources.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011 FOLLOW UP MISSION

**BASIS:** GSR Part 1: Requirement 12: *Interfaces of safety with nuclear security and with the State system of accounting for and control of nuclear material.*

*The government shall ensure that within the governmental and legal framework adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for and control of nuclear material.*

*2.39. Specific responsibilities within the governmental and legal framework shall include:*

*Assessment of the configuration of facilities and activities for the optimization of safety, with factors relating to nuclear security and to the system of accounting for and control of nuclear material taken into account;*

*Oversight and enforcement to maintain arrangements for safety, nuclear security and the system of accounting for and control of nuclear material;*

*Liaison with law enforcement agencies, as appropriate;*

*Integration of emergency response arrangements for safety related and nuclear security related incidents.*

GPF6 **Good Practice:** CSN has integrated its security inspection and oversight program into its Integrated System for Plant Oversight (SISC).

**BASIS:** Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety.

*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.*

*2.18. 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:*

*(4) Emergency preparedness and response;*

*(7) Nuclear security;*

*(8) The State system of accounting for and control of nuclear material;*

*(11) Safety in the transport of dangerous goods, including nuclear material and radioactive material;*

GPF7 **Good Practice:** CSN has been very proactive in working with multiple national organizations that are competent authorities in areas interrelated with physical

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2011  
FOLLOW UP MISSION**

security of nuclear facilities, nuclear materials and radioactive sources. This has resulted in excellent collaboration and cooperation, resulting in considerable progress being made on some very sensitive and complex security-related issues.

## 11. SUMMARY ON ASCÓ EVENT

On April 4<sup>th</sup>, after receiving the preliminary information provided by its resident inspectors on the detection of radioactive particles in off-site areas, the CSN took a number of immediate actions. Given that the event involved a real on-site and off-site radioactive release, the first priority was to gain insight on the real scope of the event and to assess the potential exposure of the workers and public and the contamination of the environment. The CSN performed a preliminary assessment of the situation, sent an inspection team to the plant and published a press release to inform the public. As further steps, the activities explained below were carried out.

The CSN emitted Technical Instructions requiring the licensee:

- Assess event consequences and prevent additional releases and contamination spread: stop HVAC systems, to improve on-site radiological controls, monitoring of people potentially affected....
- Gain knowledge about the circumstances of the event: actual situation of contamination in HVAC, on-site and off-site; sequence of events, records and internal communications, root cause analysis (MORT), etc...

Additionally, a program of regulatory inspections was launched including:

- Specific inspections in all technical areas related to the event
- Inspections for close oversight of on-site radiological survey and cleaning activities and monitoring (whole body counters) of workers and members of the public potentially affected
- Inspections to review the diagnostic activities for the Action Plan to analyse the root causes of the event and define the organizational, cultural and technical reinforcement plan (PROCURA) plan definition.

A special campaign for radiological survey and cleaning off-site was directly conducted by CSN, supported by CIEMAT and a Radiation Protection Technical Service (UTPR).

A CSN internal technical group, headed by a Commissioner, was set up for the detailed assessment of radiological consequences, supported by external organisations (CIEMAT).

A communications plan was defined with two targets: national/local authorities and public/communication media.

Technical instructions were sent to the rest of Spanish NPP requiring detailed applicability analysis of the event, lessons learned and actions to be implemented. A special program for plant site detailed radiological survey and cleaning/decontamination was required as well.

As a consequence of the event, the licensee took some organizational actions and several senior managers were replaced. Of even greater significance was the creation by the licensee in May 2008 of the ENDESA Nuclear Energy Division, which director reports directly to utility CEO. This change has had a considerable impact on the operation of the Asociación Nuclear Ascó Vandellos 2 (ANAV), as is shown by the significant increase in the economic and human resources incorporated into the organization and the transparency policy with the CSN and the public.

In addition to the ANAV organization, the new Nuclear Energy Division established a new independent unit dedicated to the oversight of all the nuclear power plants in which the company has some shares and set up a high level advisory committee made up of experts in safety-related activities, with the participation of Institute of Nuclear Power Operations (INPO) personnel and relevant national and international experts.

An in depth root cause analysis of the event was performed by the licensee in response to the CSN requirement and a comprehensive and thorough set of diagnosis analysis were carried out to identify the organizational weakness leading to the event. The PROCURA plan (2009-2012)

established by the licensee and approved by CSN address those weaknesses and is intended to promote a cultural change through the organization. This plan is complemented with a cultural and behavioral reinforcement program and a generational turnover management program. The CSN is closely overseeing the implementation of the plans.

Also a number of improvements have been incorporated in the CSN organization, policies and practices mainly related to public communication and inspection activities.

## APPENDIX I – LIST OF PARTICIPANTS

### INTERNATIONAL EXPERTS:

1. Luis <b>REYES</b>	United States Nuclear Regulatory Commission (USNRC)	<a href="mailto:Luis.Reyes@nrc.gov">Luis.Reyes@nrc.gov</a>
2. John <b>LOY</b>	Federal Authority for Nuclear Regulation (FANR)	<a href="mailto:john.loy@fanr.gov.ae">john.loy@fanr.gov.ae</a>
3. William <b>DEAN</b>	United States Nuclear Regulatory Commission (USNRC)	<a href="mailto:Bill.Dean@nrc.gov">Bill.Dean@nrc.gov</a>
4. Carl-Magnus <b>LARSSON</b>	Australian Radiation Protection & Nuclear Safety Agency (ARPANSA)	<a href="mailto:carl-magnus.larsson@arpansa.gov.au">carl-magnus.larsson@arpansa.gov.au</a>
5. Hilde <b>OLERUD</b>	Norwegian Radiation Protection Authority	<a href="mailto:Hilde.Olerud@nrpa.no">Hilde.Olerud@nrpa.no</a>

### IAEA STAFF MEMBERS

1. Gustavo <b>CARUSO</b>	Division of Nuclear Installation Safety	<a href="mailto:G.Caruso@iaea.org">G.Caruso@iaea.org</a>
2. Adriana <b>NICIC</b>	Division of Nuclear Installation Safety	<a href="mailto:A.Nicic@iaea.org">A.Nicic@iaea.org</a>
3. Marlene <b>KOBEIN</b>	Division of Nuclear Installation Safety	<a href="mailto:M.Kobein@iaea.org">M.Kobein@iaea.org</a>

### OFFICIAL CSN LIAISON OFFICER:

1. Isabel MELLADO	Nuclear Safety Council	<a href="mailto:imj@csn.es">imj@csn.es</a>
2. Juan Carlos LENTIJO	Nuclear Safety Council	<a href="mailto:jcll@csn.es">jcll@csn.es</a>

## APPENDIX II – MISSION PROGRAMME

<b>IRRS MISSION PROGRAMME</b>		
<b>Monday, 24 January 2011</b>		
<b>IRRS Opening IRRS Review Team Meeting</b>		
13:00 – 14:00	Lunch with CSN counterparts	IRRS Review Team CSN Counterparts
14:00-18:00	IRRS Opening Review Team meeting	IRRS Review Team CSN Liaison Officers
<b>Tuesday, 25 January 2011</b>		
<b>IRRS Entrance Meeting</b>		
09:00 – 11:00	Welcome, Introduction of CSN Senior Staff, IRRS Review Team and CSN Counterparts	IRRS Review Team CSN Counterparts MITYC
11:00 – 11:30	Coffee Break	
11:30 – 13:00	Module Review (All review areas)	IRRS Review Team CSN Counterparts
13:00 – 14:30	Lunch Break	
14:30 – 16:30	Module Review (All review areas) ~ S8 & S9 ( <i>L. Reyes</i> ) ~ S1 & S2 ( <i>J. Loy</i> ) ~ R2 & S15 ( <i>H. Olerud</i> ) ~ S21 & S22 ( <i>C.M. Larsson</i> ) ~ R4 & R5 ( <i>A. Nicic</i> ) ~ Physical Protection ( <i>B. Dean</i> )	IRRS Review Team CSN Counterparts
16:30 – 17:00	Coffee Break	
17:00 -	IRRS Daily Review Team Meeting	IRRS Review Team CSN Liaison Officers
<b>Wednesday, 26 January 2011</b>		
<b>Daily Discussions / Interviews</b>		
09:00 – 10:30	Module Review (All review areas) ~ S10 & S11 ( <i>L. Reyes</i> ) ~ S3 & S5 ( <i>J. Loy</i> ) ~ S16 ( <i>H. Olerud</i> ) ~ R3 ( <i>C.M. Larsson</i> ) ~ S23 & S24 ( <i>A. Nicic</i> ) ~ Physical Protection ( <i>B. Dean</i> )	IRRS Review Team CSN Counterparts
10:30 – 11:00	Coffee Break	
11:00 – 13:00	Continuation Module Review (All review areas)	IRRS Review Team CSN Counterparts
13:00 – 14:30	Lunch Break	
14:30 – 16:30	Module Review (All review areas) ~ S12 & S13 ( <i>L. Reyes</i> ) ~ S6 & S7 ( <i>J. Loy</i> ) ~ S17 ( <i>H. Olerud</i> ) ~ R3 ( <i>C.M. Larsson</i> ) ~ S25 & S26 ( <i>A. Nicic</i> ) ~ Physical Protection ( <i>B. Dean</i> )	IRRS Review Team CSN Counterparts
16:30 – 17:00	Coffee Break	

## IRRS MISSION PROGRAMME

17:00 -	IRRS Daily Review Team Meeting	IRRS Review Team CSN Liaison Officers
<b>Thursday, 27 January 2011</b>		
<b>Daily Discussions / Interviews</b>		
09:00 – 10:30	Module Review (All review areas) ~ <i>R1 &amp; S14 (L. Reyes)</i> ~ <i>S18, S19 &amp; S20 (J. Loy)</i> ~ <i>S27 (A. Nicic)</i> ~ <i>Physical Protection (B. Dean)</i>	IRRS Review Team CSN Counterparts
10:30 – 11:00	Coffee Break	
11:00 – 13:00	Module Review (All review areas)	IRRS Review Team CSN Counterparts
13:00 – 14:30	Lunch Break	
14:30 – 16:30	Review of the CSN activities related to the radioactive particles release event in Ascó NPP	IRRS Review Team CSN Counterparts
16:30 – 17:00	Coffee Break	
17:00 -	IRRS Daily Review Team Meeting	IRRS Review Team CSN Liaison Officers
<b>Friday, 28 January 2011</b>		
<b>Daily Discussions / Interviews</b>		
09:00 – 10:30	Module Review (All review areas)	IRRS Review Team CSN Counterparts
10:30 – 11:00	Coffee Break	
11:00 – 13:00	Module Review (All review areas)	IRRS Review Team CSN Counterparts
13:00 – 14:30	Lunch Break	
14:30 – 16:30	Module Review (All review areas)	IRRS Review Team CSN Counterparts
16:30 – 17:00	Coffee Break	
17:00 -	IRRS Daily Review Team Meeting	IRRS Review Team CSN Liaison Officers
<b>Saturday, 29 January 2011</b>		
<b>IRRS Review Team meeting and Mission report submission</b>		
09:30 -	IRRS Daily Review Team Meeting - Report writing	IRRS Review Team
<b>Sunday, 30 January 2011</b>		
<b>Submission of IRRS Draft Mission report to Spain</b>		
09:00 – 14:00	Social Visit and Lunch	IRRS Review Team CSN Counterparts
15:00	Draft IRRS mission report to be sent to CSN	IRRS Review Team
<b>Monday, 31 January 2011</b>		
<b>Plenary Meeting</b>		
08:30 – 11:00	Internal CSN draft report discussion	CSN Counterparts
11:00 – 13:00	Plenary meeting – IRRS Review Team and CSN counterparts	IRRS Review Team CSN Counterparts
13:00 – 14:30	Lunch Break	
14:30 – 16:00	Continuation if needed: Plenary meeting – IRRS Review Team and CSN counterparts	IRRS Review Team CSN Counterparts

## IRRS MISSION PROGRAMME

16:00 – 16:30	Coffee Break	
17:00 -	IRRS Daily Review Team Meeting	IRRS Review Team CSN Liaison Officers
<b>Tuesday, 1 February 2011</b>		
<b>Exit Meeting</b>		
10:30 – 12:00	Exit Meeting	IRRS Review Team CSN Counterparts MITYC

**APPENDIX III – LIST OF MISSION COUNTERPARTS**

<b>item</b>	<b>Subject Area</b>	<b>IRRS Experts</b>	<b>Lead Counterparts</b>
<b>1</b>	<b>LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES</b>	Mr John Loy	Ms V. Mendez Mr J.L. Butragueno Mr. J.C. Lentijo
<b>2</b>	<b>RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>	<i>Area not reviewed as there were no recommendations or suggestions in the 2008 IRRS mission</i>	
<b>3</b>	<b>ORGANIZATION OF THE REGULATORY BODY</b>	Mr John Loy	Ms V. Mendez Mr J.L. Butragueno Mr. J.C. Lentijo
<b>4</b>	<ul style="list-style-type: none"> <li><b>ACTIVITIES OF THE REGULATORY BODY</b></li> </ul>		
<b>4-1</b>	<b>AUTHORIZATION</b>		
<b>4.1.1.</b>	<b>Nuclear Power Plants</b>	<i>Area not reviewed as there were no recommendations or suggestions in the 2008 IRRS mission</i>	
<b>4.1.2.</b>	<b>Radiation Facilities – Industrial and Medical Practices, Radiation Protection and Dosimetry Services</b>		
<b>4.1.3.</b>	<b>Decommissioning, Waste and Remediation and Environmental Surveillance</b>		
<b>4.2.</b>	<b>REVIEW AND ASSESSMENT</b>		
<b>4.2.1</b>	<b>Nuclear Power Plants</b>	<i>Area not reviewed as there were no recommendations or suggestions in the 2008 IRRS mission</i>	
<b>4.2.2.</b>	<b>Radiation Facilities – Industrial and Medical Practices, Radiation Protection and Dosimetry Services</b>		

item	Subject Area	IRRS Experts	Lead Counterparts
4.2.3.	Decommissioning, Waste and Remediation and Environmental Surveillance		
4.3.	<ul style="list-style-type: none"> <li>DEVELOPMENT OF REGULATIONS AND GUIDES</li> </ul>		
4.3.1.	Nuclear Power Plants	Mr Luis Reyes	Ms V. Mendez Mr J. Zarzuela Ms I. Mellado Mr I. Recarte Ms MJ Munoz J. Gil Huguet (Unificar tratamiento)
4.3.2.	Radiation Facilities – Industrial and Medical Practices, Radiation Protection and Dosimetry Services	<i>Area not reviewed as there were no recommendations or suggestions in the 2008 IRRS mission</i>	
4.3.3.	Decommissioning, Waste and Remediation and Environmental Surveillance		
4.4.	INSPECTION AND ENFORCEMENT		
4.4.1.	Nuclear Power Plants	Mr Luis Reyes	Mr JI Calvo Mr J. Zarzuela Ms I. Mellado R. Cid M. Teresa Sanz
4.4.2.	Radiation Facilities – Industrial and Medical Practices, Radiation Protection and Dosimetry Services	Ms Hilde Olerud	M. Rodriguez C. Alvarez Ignacio Amor
4.4.3.	Decommissioning, Waste and Remediation and Environmental Surveillance	<i>Area not reviewed as there were no recommendations or suggestions in the 2008 IRRS mission</i>	

item	Subject Area	IRRS Experts	Lead Counterparts
5	SAFETY AND SECURITY OF RADIOACTIVE SOURCES	Ms Hilde Olerud	M. Rodriguez C. Alvarez Ignacio Amor
6	TRANSPORT OF RADIOACTIVE WASTE	Ms Hilde Olerud	F. Zamora
7	EMERGENCY PREPAREDNESS	Mr John Loy	Ramon De La Vega
8	INFRASTRUCTURE FOR RADWASTE, DECOMMISSIONING AND REMEDIATION AND ENVIRONMENTAL SURVEILLANCE	Mr Carl-Magnus Larsson	Lucila Ramos C. Ruiz
9	MANAGEMENT SYSTEM FOR REGULATORY BODY	Ms Adriana Nicic	A. Cepas
10	PHYSICAL PROTECTION IN NUCLEAR INSTALLATIONS	Mr Bill Dean	P. Lardiez

**APPENDIX IV – RECOMMENDATIONS AND SUGGESTIONS FROM THE 2008 IRRS MISSION**

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
1	<b>LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES</b>	S1	<b>Suggestion:</b> The CSN should consider, in line with the practice adopted in other countries, whether to propose a change in the Law on Fees and Public Prices that would apply a base annual fee and charges for regulatory activities generated by licence holders so as to establish a ‘price signal’ for operators.
		G1	<b>Good Practice:</b> The detailed statement of operator responsibility now established in the Nuclear Energy Law by the 2007 amendments.
		S2	<b>Suggestion:</b> In implementing the new legal provisions for the operation of the advisory committee on transparency and communications, the potential for there to be unintended adverse impacts of transparency and communications on safety should be carefully considered by CSN and debated with the advisory committee.
2	<b>RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>	<i>No recommendation, suggestion or good practice identified.</i>	
3	<b>ORGANIZATION OF THE REGULATORY BODY</b>	S3	<b>Suggestion:</b> CSN should consider an approach that will facilitate the recruitment of staff at above the base-level for technical staff and non technical professionals.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S5	<b>Suggestion:</b> The plans to enhance the organizational expertise in risk assessment, operating experience and human organization factors should be implemented with high priority. Other resource skill allocations should consider new facilities being proposed as well as the new demands in security, communications, international relations and compliance with law 33/2007 regarding radiation protection of patients.
		S6	<b>Suggestion:</b> The training of CSN inspectors should consider the addition of soft skills training such as communications, report writing and conflict resolution.
		S7	<b>Suggestion:</b> CSN should use its authority to establish a technical advisory committee.
4	<b>ACTIVITIES OF THE REGULATORY BODY</b>		
	<b>AUTHORIZATION</b>	<i>No recommendation, suggestion or good practice identified.</i>	

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	<b>REVIEW AND ASSESSMENT</b>	G2	<b>Good Practice:</b> CSN has developed and implemented a user-friendly PSA tool for use by staff not expert in the understanding of PSAs. This contains detailed plant data for each of Spain's NPPs and supports the SISC system and its Significance Determination Process. This PSA tool enables all CSN technical staff, and not simply those who are experts in PSA, to understand the plant systems and operational conditions important to safety. In addition a special PSA tool is available on the CSN intranet for use by all inspectors The tool facilitates the risk-informed selection of the SSC for the SISC inspection.
		G3	<b>Good Practice:</b> Regular meetings with Spanish radiation protection societies and the Spanish health physics society are also organized to discuss review and assessment issues.
	<b>DEVELOPMENT OF REGULATIONS AND GUIDES</b>	S8	<b>Suggestion:</b> The planned CSN policy and overall strategy for the development of binding regulations and guides should be developed in the near future. It should respond to needs identified and experience made with the current activities to further enhance consistency and completeness of the Spanish 'regulatory pyramid'. The approach should ensure that the requirements imposed by the regulator
		S9	<b>Suggestion:</b> CSN should compile a uniform glossary to be used for all legally based regulatory documents. This glossary should also enable and support the proper understanding or interpretation of the respective language used in the countries of origin, as well as in IAEA standards.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		G4	<b>Good practice:</b> CSN practices a well based and thorough approach that requires the licensees to systematically assess advances in international standards and to take relevant standards into account and to make them binding for licensees. The practice of annual reviews of the development of safety standards related to the licensing base as well as considering additional standards and practices in the context of license renewal processes supports continuous development of plant safety.
		S10	<b>Suggestion:</b> Regarding major backfittings, the state of the art of backfitting technology for comparable designs in other countries – not only the countries of origin – should be taken into account for more detailed conditions and requirements to the licensees.
		G5	<b>Good practice:</b> The CSN approach to keep track of the development of regulations and guides in countries of origin to take into consideration comments from interested parties and the feedback of experience is very systematic and comprehensive.
		S11	<b>Suggestion:</b> CSN should address possible inconsistencies for Spanish regulations resulting from requirements from foreign sources as the countries of origin of design or the IAEA more directly. The experience made with the integration of different sources into the Spanish system of regulations and guides should be reported back for consideration by the respective institutions to promote resolution of such inconsistencies.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		G6	<b>Good practice:</b> The material available on the CSN web site, including guides and training courses in radiation protection, is comprehensive for the various practices and is an efficient tool to contribute to safety improvements among the many operators involved in radiation facilities or using X rays for medical diagnostic purposes.
	<b>INSPECTION AND ENFORCEMENT</b>	G7	<b>Good practices:</b> CSN management of the inspections with all the documents available on the intranet across all facilities and activities is highly effective. The processes include the regular review of inspections and their findings as well as the follow up of plans with associated resources. The conduct of the inspection programmes in this area as well as others covered by the IRRS review is made in a transparent and traceable way.
G8		<b>Good practice:</b> The SIC'S programme results are thoroughly presented on the CSN web site. The status of the utility is clearly presented and the related safety questions if any are presented in an easily understandable way. Also in-depth information can be found.	
S12		<b>Suggestion:</b> CSN should evaluate the effectiveness of the new SIC'S inspection programme together with the other inspection, review and assessment activities with respect to the coverage of the issues and activities important to safety.	

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S13	<b>Suggestion:</b> CSN should consider the balance of the resources allocated to the human and organizational issues as well as the number of inspections in which these issues are addressed. In planning inspections of human and organizational factors, CSN should also consider what is an appropriate level and way of addressing management and policy issues of the licensees.
		R1	<b>Recommendations:</b> CSN should implement a systematic way of compiling and presenting the results obtained, the trends and consequences drawn from inspections and review and assessment for all nuclear installations where applicable, and should give feedback to the licensee. This should be undertaken on a periodic basis.
		S14	<b>Suggestion:</b> As inspection reports of the nuclear power plants and fuel fabrication facility as well as the SIC'S information package are being put onto the CSN web site, CSN should have a standard format for presenting the scope of the inspections and the findings together with its evaluation of the safety significance and the information of the nuclear power plant should be in one place. CSN should also assess the benefit of presenting inspection reports with utility comments and their resolution at the web site.
		G9	<b>Good practice:</b> Inspection reports for radiation facilities and X ray facilities for medical diagnosis are published on the CSN web-site. The only information that is excluded is information that is considered sensitive (personal data, commercial, security aspects etc). This makes the CSN activity transparent to the public, raises public credibility in the regulatory system and can promote the safety of the facilities.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		R2	<b>Recommendation:</b> From all its inspections in x-ray diagnostic and radiation facilities, CSN should build and express an opinion about the results obtained, the trends and consequences drawn in the different practices using radioactive sources, and to give feedback to the licensee. This should be undertaken in a periodic way.
		S15	<b>Suggestion:</b> CSN should consider to upgrade their internal procedures to a formal procedure for inspection of Dosimetry Services.
		G10	<b>Good practice:</b> The CSN inspection programme for facilities for operational waste disposal and for discharge control, and the verification of the protection of the public and the environment from operating and decommissioned facilities through environmental monitoring, is highly structured, conducted in a highly competent manner, and followed up according to clear procedures.
5	<b>SAFETY AND SECURITY OF RADIOACTIVE SOURCES</b>	S16	<b>Suggestion:</b> CSN should establish a formal mechanism for exchange of information with the Customs about notification that a radioactive source has actually entered or left the country to make it fully traceable.
		G11	<b>Good practice:</b> Spain has established strong measures for ensuring effective management of sources at the end of their life; a condition of license that there be arrangements for return to the supplier or for proper disposal or storage, supported by financial guarantees. In exceptional circumstances confiscation of the source and its recovery from public fund is provided.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		G12	<b>Good practice:</b> Spain has a consistent and stable policy of organizing and carrying out state campaigns for restoring appropriate control over orphan sources. IAEA methodology for combined administrative and physical search of orphan sources is comprehensively implemented.
6	<b>TRANSPORT OF RADIOACTIVE MATERIAL</b>	S17	<b>Suggestion:</b> To support the work of the Committee for the Coordination of the transport of dangerous goods of the Ministry of Public Works, Memoranda of Understanding or equivalent should be established where possible, with the other competent authorities with competences in the inspection of dangerous goods.
		G13	<b>Good Practice:</b> The Transport Management Database System incorporating databases on packages subject to approval, packages not subject to approval, carriers, Type B(U) packages, authorizations, inspections, and incidents and all other relevant documentation is considered to be comprehensive, user friendly and a practical management tool.
		G14	<b>Good Practice:</b> To assist all relevant stakeholders the CSN has for a number of years produced a detailed correlation table between the current IAEA TS-R-1 and the current ADR by theme, paragraph number and a comment indicating the relevant changes in each document. This proactive approach is very practical and meets the needs of the operators, staff etc
7	<b>EMERGENCY PREPAREDNESS</b>	S18	<b>Suggestion:</b> CSN should upgrade guidance on radiological emergencies to support use of the IAEA threat assessment categories.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S19	<b>Suggestion:</b> CSN should continue developing planning for <i>the actions to be taken after an emergency.</i> , taking into account the specific national conditions and international recommendations.
		S20	<b>Suggestion:</b> CSN should consider extending the existing national guidance for emergency (group one) workers by introducing a more selective specification of conditions based on IAEA EPR-method-2003 -.
		G15	<b>Good practice:</b> CSN established an integrated network-based database system for management, control and recording of doses, enabling control of doses received by emergency worker. Effective management of dose records significantly contributes to an effective emergency management and protection of emergency workers.
		G16	<b>Good practice:</b> An effective framework for managing the situation in case of uncontrolled source emergencies in metallurgy recycling sector has been established. Adaptation of the Protocol for Radiological Surveillance of Metal Recycling, a Collaboration of Government and Industry, with effective involvement of CSN, ensures a high level of readiness for this type of emergency at national level.
8	<b>INFRASTRUCTURE FOR RADWASTE, DECOMMISSIONING AND REMEDIATION AND ENVIRONMENTAL SURVEILLANCE</b>	G17	<b>Good practice:</b> The national system involves the obligation of ENRESA to draw up the General Waste Management Plan (PGRR), which cover all waste streams and also incorporates the views of different affected parties in the establishment of the national strategies. The PGRR is a comprehensive document that allows for assessment of interdependencies and priorities.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S21	<b>Suggestion:</b> CSN should work towards, and the Government should consider, adjusting the procedure for approval of the General Radioactive Waste Plan, or PGRR, so that the plan is submitted to the Ministry of Industry, Tourism and Commerce (MITYC), together with a technical review of the safety- and radiation protection- related matters of the same document by the CSN, to assist the Ministry in judging the technical considerations underpinning the strategy laid out in the PGRR.
		S22	<b>Suggestion:</b> The CSN should work with the Competent Authorities to regulate the establishment and maintenance of a national centralised inventory of existing and anticipated radwaste, including also waste that could be generated outside regulated facilities.
		R3	<b>Recommendation:</b> CSN should work with other competent authorities to encourage the development and communication of plans for final disposal of spent fuel and HLW, and contribute to setting the appropriate targets and conditions that would, from all points of view, govern the process, so that there is no unnecessary delay in the solution of the problem, and that also gradually would improve the estimates of future costs for the final radwaste management.
		G18	<b>Good practice:</b> In the area of decommissioning of nuclear power plants and other fuel cycle facilities, an infrastructure has developed and matured over the years, including regulatory experience, that allow decommissioning projects to be carried out efficiently and with minimal delays. This may serve as an international benchmark.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
9	<b>MANAGEMENT SYSTEM</b>	R4	<b>Recommendation:</b> CSN should formalise and implement an internal audit programme of the management processes. The programme should ensure that all processes are audited within a defined time period. To support this programme a number of internal auditors should be selected among the staff and given adequate training. In connection with the audit programme, a systematic approach to the management of non-conformances of processes and products should be developed and formalised.
R5		<b>Recommendation:</b> CSN should develop a methodology and implement management system reviews to be conducted at planned intervals by internal or/and external resources. This programme should ensure the continuing suitability and effectiveness of the management system as a whole and its ability to enable the objectives of the organisation to be accomplished.	
S23		<b>Suggestion:</b> CSN should insert into the management system manual a more concise organizational policy statement which gives a clear message from the Council to stakeholders about what they can expect the CSN to deliver.	
S24		<b>Suggestion:</b> To support management self-assessments, CSN should perform assessments (surveys) of the regulatory (safety) culture among all staff at planned intervals and develop a mechanism to feedback and act on the results. These surveys could be included in the planned working climate surveys.	
S25		<b>Suggestion:</b> CSN should implement an up to date software application on the intranet of the process map and make it possible to open all attached documents from the map.	

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S26	<b>Suggestion:</b> CSN should implement a mechanism to identify opportunities for improvement of the management system as well as to monitor improvement actions and check the effectiveness of the improvements. An instrument for this could be mailboxes on the intranet, attached to each management system process, for collecting comments and suggestions from the staff.
		S27	<b>Suggestion:</b> CSN should develop a procedure to manage and assess its organisational change.
		G19	<b>Good Practice:</b> CSN has a well developed documentation and information management system on the intranet that supports a consistent and efficient regulatory decision-making by providing staff with prompt access to all necessary documents as well as reference information such as previous regulatory decisions and safety assessments. The system also holds design and operational documentation from the regulated facilities.
X	<b>PHYSICAL PROTECTION IN NUCLEAR INSTALLATIONS</b>	<i>As a part of this IRRS Mission, at the invitation of CSN, a team reviewed the legal and regulatory aspects of nuclear security for nuclear and radioactive material in use, storage and transport as it relates solely to the roles and responsibilities of CSN. As part of its efforts the team observed a joint physical protection inspection conducted by CSN, the national police (CPN) and the Guardia Civil (GC.). The team also interviewed representatives of the Ministry of Interior and Ministry of Industry, Tourism and Trade to assess the interface and coordination between CSN and these</i>	

**APPENDIX V – RECOMMENDATIONS/SUGGESTIONS AND GOOD PRACTICES FROM THE 2011 IRRS FOLLOW UP MISSION**

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
3	<b>ORGANIZATION OF THE REGULATORY BODY</b>	SF1	<b>Suggestion:</b> That the CSN establish a formal policy establishing the circumstances in which it will consider seeking external expert advice to assist the Council in making regulatory decisions, including through the establishment of a standing or ad hoc technical advisory bodies.
	<b>ACTIVITIES OF THE REGULATORY BODY</b>	GPF1	<b>Good Practice:</b> CSN issued IS-19 instruction on the management system based on the IAEA GS-R-3. This instruction requires the licensee’s strategic plan with the associated investments and human resources needs for the following four years be discussed in a high level meeting between the CSN plenary and the licensee top management.
		GPF2	<b>Good practice:</b> The Framework co-operation agreement between the Ministry for Health and the CSN signed in 2010 is an important initiative to coordinate national efforts on radiation protection.
7	<b>EMERGENCY PREPAREDNESS</b>	GPF3	<b>Good Practice:</b> The CSN’s successful carrying out of a field exercise with other relevant agencies as a part of the table-top INEX 4 exercise on radiological emergency consequence management.
8	<b>INFRASTRUCTURE FOR RADWASTE, DECOMMISSIONING AND REMEDIATION AND ENVIRONMENTAL SURVEILLANCE</b>	GPF4	<b>Good practice:</b> The arrangements for a transparent and technically sound siting process for the Central Temporary Storage (CTS) facility and its associated technical centre is good practice

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		RF1	<b>Recommendation:</b> CSN should continue to work with relevant competent authorities and other bodies to facilitate the process for siting a disposal facility for spent fuel and high level waste, as laid out in the 6 <sup>th</sup> PGRR and as approved by the Government. CSN should take the experiences from the siting of the CTS facility into account and contribute
9	<b>MANAGEMENT SYSTEM</b>	GPF5	<b>Good Practice:</b> The internal audit process developed by CSN, with strong support from the senior management and staff participation, was implemented in a timely manner and allows the organization to assess the effectiveness of its regulatory processes and to identify opportunities for improvement.
X	<b>PHYSICAL PROTECTION IN NUCLEAR INSTALLATIONS</b>	GPF6	<b>Good Practice:</b> CSN has integrated its security inspection and oversight program into its Integrated System for Plant Oversight (SISC).
		GPF7	<b>Good Practice:</b> CSN has been very proactive in working with multiple national organizations that are competent authorities in areas interrelated with physical security of nuclear facilities, nuclear materials and radioactive sources. This has resulted in excellent collaboration and cooperation, resulting in considerable progress being made on some very sensitive and complex security-related issues.

## APPENDIX VI – REFERENCE MATERIAL PROVIDED BY CSN

<b>[1]</b>	<b>CSN ACTION PLAN FROM THE 2008 IRRS MISSION</b>
	<ul style="list-style-type: none"> <li>➤ <i>Action Plan on the Recommendations and Suggestions from the 2008 Mission</i></li> </ul>
<b>[2]</b>	<b>LAWS</b>
	<ul style="list-style-type: none"> <li>➤ <i>1700 Law 11/2009, of October 26th, regulating Limited Investment Companies Quoted on the Real Estate Market</i></li> </ul>
<b>[3]</b>	<b>RESOLUTIONS</b>
	<ul style="list-style-type: none"> <li>➤ <i>Resolution by the Directorate General for Energy Policy and Mines authorising ENRESA to modify the design of the solid radioactive waste disposal nuclear facility at Sierra Albarrana (El Cabril), for the disposal of very low level radioactive waste.</i></li> <li>➤ <i>Resolution of December 21st 2009 by the Secretariat of State for Climate Change formulating the environmental impact statement with regard to the project Dismantling and decommissioning of the José Cabrera nuclear power plant, in the municipal territory of Almonacid de Zorita, Guadalajara.</i></li> <li>➤ <i>Resolution of December 23rd 2009 by the Secretariat of State for Energy initiating the process of public proposals for the selection of candidate municipalities to house the site of the Centralised Temporary Storage (CTS) facility for spent nuclear fuel and high level radioactive waste and associated technology centre.</i></li> </ul>
<b>[4]</b>	<b>ROYAL DECREES</b>
	<ul style="list-style-type: none"> <li>➤ <i>4172 ROYAL DECREE LAW 5/2005, OF 11th MARCH</i></li> <li>➤ <i>ROYAL DECREE 229/2006, of February 24th, on the control of high level encapsulated radioactive sources and orphan sources.</i></li> <li>➤ <i>ROYAL DECREE 775/2006, dated 23rd June, creating the Interministerial Committee for the establishment of the criteria that must be met by the site of the centralised spent nuclear fuel and high-level waste temporary storage facility, and of its associated technology centre.</i></li> <li>➤ <i>RD 1085/2009, of 3<sup>rd</sup> July, approving the Regulation on Installation and Use of X-ray Apparatus for Medical Diagnosis.</i></li> <li>➤ <i>Royal Decree 1838/1999, of 3 December, approving the Regulation on Nuclear and Radioactive Facilities, modified by Royal Decree 35/2008, of 18 January</i></li> </ul>
<b>[5]</b>	<b>CSN INSTRUCTIONS</b>
	<ul style="list-style-type: none"> <li>➤ <i>- The Nuclear Safety Council's Instruction IS-26, of 16<sup>th</sup> June 2010, on basic nuclear safety requirements applicable to nuclear installations.</i></li> <li>➤ <i>Nuclear Safety Council's INSTRUCTION IS-15, of 31st October 2007, on the requirements for monitoring the effectiveness of maintenance at nuclear power plants.</i></li> <li>➤ <i>Instruction IS-14 of the Nuclear Safety Council, of 24th October 2007, on the CSN Resident Inspection at Nuclear Power Plants</i></li> <li>➤ <i>Nuclear Safety Council's Instruction IS-16, of 23rd January 2008, regulating the periods of time which documents and records of radioactive facilities must be remain filed for.</i></li> <li>➤ <i>The Nuclear Safety Council's INSTRUCTION IS-17, of 30th January, 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.</i></li> <li>➤ <i>Nuclear Safety Council's Instruction IS-18, of 2nd April 2008, on the criteria applied by the CSN to demand from the licensees of radioactive facilities the reporting of radiological events and incidents</i></li> </ul>

	<ul style="list-style-type: none"> <li>➤ <i>Instruction IS-19, on the requirements of the nuclear facilities management system</i></li> <li>➤ <i>Instruction IS-20, on safety requirements relating to spent fuel storage casks</i></li> <li>➤ <i>Instruction IS-21</i></li> <li>➤ <i>Nuclear Safety Council Instruction number IS-22, of July 1st 2009, on safety requirements for the management of ageing and long-term operation of nuclear power plants</i></li> <li>➤ <i>Instruction IS-23, on in-service inspection at nuclear power plants</i></li> <li>➤ <i>Nuclear Safety Council's Instruction IS-24, of 19<sup>th</sup> May 2010, regulating the filing and periods of retention of the documents and records of nuclear facilities.</i></li> <li>➤ <i>Nuclear Safety Council Instruction IS-25, of 9th June 2010, on criteria and requirements on the performance of probabilistic safety assessments and their applications for nuclear power plants.</i></li> <li>➤ <i>The Nuclear Safety Council's Instruction IS-27, of 16<sup>th</sup> June 2010, on general nuclear power plant design criteria.</i></li> </ul>
<b>[6]</b>	<b>ORDER</b>
	<ul style="list-style-type: none"> <li>➤ <i>Order ITC/204/2010 of 1 February, authorising the transfer of ownership of the Jose Cabrera nuclear power plant from the company Gas Natural, S.A. to the Empresa Nacional de Residuos Radiactivos, S.A. and authorising the latter to carry out decommissioning</i></li> </ul>
<b>[7]</b>	<b>OTHER</b>
	<ul style="list-style-type: none"> <li>➤ <i>Management System Manual</i></li> </ul>

## APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- [1.] **IAEA SAFETY STANDARDS SERIES GS-R-1** - *Legislative and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*
- [2.] **IAEA SAFETY STANDARDS SERIES GS-G-1.1** -*Organization and Staffing of the Regulatory Body for Nuclear Facilities*
- [3.] **IAEA SAFETY STANDARDS SERIES GS-G-1.2** -*Review and Assessment of Nuclear Facilities by the Regulatory Body*
- [4.] **IAEA SAFETY STANDARDS SERIES GS-G-1.3** -*Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body*
- [5.] **IAEA SAFETY STANDARDS SERIES GS-G-1.4** -*Documentation for use in Regulation of Nuclear Facilities*
- [6.] **IAEA SAFETY STANDARDS SERIES GS-G-1.5** - *Regulatory Control of Radiation Sources*
- [7.] **IAEA SAFETY STANDARDS SERIES GS-R-2**-*Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements*
- [8.] **IAEA SAFETY STANDARDS SERIES GS-R-3** -*Management System for Facilities and Activities*
- [9.] **IAEA SAFETY STANDARDS SERIES NS-R-1** -*Safety of Nuclear Power Plants: Design Safety Requirements*
- [10.] **IAEA SAFETY STANDARDS SERIES NS-R-2** -*Safety of Nuclear Power Plants: Operation Safety Requirements*
- [11.] **IAEA SAFETY STANDARDS SERIES NS-R-4** -*Safety of Research Reactors*
- [12.] **IAEA SAFETY STANDARDS SERIES NS-G-4.1** -*Commissioning of Research Reactors*
- [13.] **IAEA SAFETY STANDARDS SERIES SS115** -*International Basic Safety standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources*
- [14.] **IAEA SAFETY STANDARDS SERIES TS-R-1** - *Regulations for the Safe Transport of Radioactive Material*
- [15.] **IAEA SAFETY STANDARDS SERIES WS-G-2.1** -*Decommissioning of Nuclear Power Plants and Research Reactors*
- [16.] **IAEA SAFETY STANDARDS SERIES WS-G-2.2** -*Decommissioning of Medical, Industrial and Research Reactors*
- [17.] **IAEA SAFETY STANDARDS SERIES WS-R-1** -*Near Surface Disposal of Radioactive Waste*
- [18.] **IAEA SAFETY STANDARDS SERIES WS-R-2** -*Predisposal Management of Radioactive Waste including Decommissioning*
- [19.] **IAEA SAFETY STANDARDS SERIES WS-G-2.3** -*Regulatory Control of Radioactive Discharges to the Environment*
- [20.] **IAEA SAFETY STANDARDS SERIES WS-G-2.4** -*Decommission of Nuclear Fuel Cycle Facilities*
- [21.] **IAEA SAFETY STANDARDS SERIES WS-G-2.5** -*Predisposal Management of Low and Intermediate Level Radioactive Waste*
- [22.] **IAEA SAFETY STANDARDS SERIES WS-G-2.6** -*Predisposal Management of High Level Radioactive Waste*
- [23.] **IAEA SAFETY STANDARDS SERIES WS-G-2.7** -*Management of Waste from the use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education*

- [24.] **IAEA SAFETY STANDARDS SERIES WS-R-3** *-Remediation of areas contaminated by past activities and accidents*
- [25.] **IAEA SAFETY STANDARDS SERIES WS-R-5** *-Decommissioning of facilities using Radioactive Material*
- [26.] **IAEA SAFETY STANDARDS SERIES WS-G-6.1** *-Storage of Radioactive Waste*
- [27.] **IAEA SAFETY STANDARDS SERIES RS-G-1.7** *-Application of the Concepts of Exclusion, Exemption and Clearance*
- [28.] **IAEA SAFETY STANDARDS SERIES RS-G-1.8** *-Environmental and Source monitoring for Purpose of Radiation Protection*
- [29.] **IAEA SAFETY STANDARDS SERIES RS-G-1.9** *-Categorization of Radioactive Sources,*
- [30.] **IAEA CODE OF CONDUCT** *on the Safety and Security of Radioactive Sources*
- [31.] **IAEA CODE OF CONDUCT** *on the Safety of Research Reactors*
- [32.] **IAEA GUIDANCE** *on the Import and Export of Radioactive Sources*
- [33.] **IAEA SAFETY SERIES NO. 111-G-1.1** *- Classification of Radioactive Waste*
- [34.] **SAFETY SERIES NO. 35 – G2** *-Safety in the Utilization and Modification of Research Reactors*
- [35.] **IAEA TECDOC 1388** *-Strengthening control over radioactive sources in authorized use and regaining control over orphan source national strategies*
- [36.] **INSAG SERIES NO. 17** *-Independence in Regulatory Decision Making*
- [37.] **INSAG SERIES NO. 20** *-Stakeholder Involvement in Nuclear Issues*
- [38.] **INSAG SERIES NO. 21** *-Strengthening the Global Nuclear Safety Regime*
- [39.] **IAEA LEGAL SERIES NO.14** *- Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency*

## APPENDIX VIII – CSN ORGANIZATIONAL CHART



