



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

Montrouge, France

2 to 9 October 2017

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service
IRRS





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Mission date: *2 to 9 October 2017*

Regulatory body: *ASN - Autorité de sûreté nucléaire*

Location: *15, rue Louis Lejeune, CS 70013, 92541 Montrouge Cedex, France*

Regulated facilities and activities in the scope: *Nuclear power plants, fuel cycle facilities, research reactors, waste management facilities, former uranium mining, uses of radiation sources in research, industry and transport, medical exposure, occupational exposure, decommissioning*

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 France, an international team of senior safety experts met representatives of the Autorité de Sûreté Nucléaire (ASN), the Institut de Radioprotection et de Sûreté Nucléaire (IRSN) and the Ministère de la Transition Écologique et Solidaire (MTES) from 2 to 9 October 2017 to conduct the IRRS follow-up mission. The peer review took place at the headquarters of ASN in Montrouge. The purpose of the IRRS follow-up mission was to review the measures undertaken following the recommendations and suggestions of the 2014 IRRS Mission.

The IRRS team consisted of seven senior regulatory experts from seven IAEA Member States and three IAEA staff members. The review compared the regulatory framework for safety in France against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and their counterparts from France in the areas covered by the IRRS mission.

The IRRS team carried out a review of the measures undertaken following the recommendations and suggestions of the 2014 IRRS mission which assessed the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection, enforcement, and the development and content of regulations and guides; emergency preparedness and response; safe transport of radioactive material; radioactive waste management and decommissioning; control of medical exposures; control of radioactive discharges and materials for clearance; environmental monitoring; occupational radiation protection; and the interface between nuclear safety and security.

The mission included interviews and discussions with ASN, IRSN and MTES staff. The IRRS team was provided with advance reference material and comprehensive documentation including the status of the recommendations and suggestions set out in the initial IRRS mission report.

The IRRS team concluded that the recommendations and suggestions from the 2014 IRRS mission have been taken into account systematically based on a comprehensive action plan. Significant progress has been made in all areas and many improvements have been implemented.

During this follow-up mission, the IRRS team determined that 14 out of 16 recommendations and 26 out of 30 suggestions, made by the 2014 IRRS mission, have been effectively addressed and therefore could be considered closed or closed on the basis of progress made and confidence in the effective completion. One new suggestion was identified. The recommendations and suggestions which remain open pertain predominately to the ASN efforts to secure sufficient human and financial resources; and complete regulatory guidance documents.

Based on the findings of the review, the IRRS team made the following general observations:

- The Government and ASN have made considerable effort in revising the legal and regulatory framework to address the findings from the 2014 IRRS mission and further enhance its alignment with the IAEA Safety Standards. This includes new provisions about inspection and enforcement powers for ASN. ASN continues to finalise the development of new regulations, guides and procedures.
- ASN has made substantial progress in implementing a graded approach into its activities, especially for the authorization and inspection of radiation sources and facilities.

- ASN has made significant progress in enhancing its management system and published many new procedures. ASN has developed policy statements incorporating safety culture and still has to incorporate safety culture aspects in its training, self-assessment and management system.
- Since the 2014 IRRS mission some additional financial and personnel resources have been added and ASN has introduced efficiencies across its activities and improved its resource planning. ASN needs to continue to focus on resource management to assure it is able to meet upcoming work such as periodic safety reviews, the life extension of nuclear power plants and new responsibilities such as supply chain oversight and radioactive source security.
- Additional effort is needed to better take into account IAEA emergency classification requirements.
- ASN conducted a successful audit of IRSN and is working with IRSN to improve ASN access to the National Dose Register (SISERI).

An IAEA press release was issued at the end of the mission.

I. INTRODUCTION

At the request of the Government of France, an international team of senior safety experts met representatives of the the Autorité de Sûreté Nucléaire (ASN), the Institut de Radioprotection et de Sûreté Nucléaire (IRSN) and the Ministère de la Transition Écologique et Solidaire (MTES) from 2 to 9 October 2017 to conduct the IRRS follow-up mission. The peer review took place at the headquarters of ASN in Montrouge. The purpose of the IRRS follow-up mission was to review the measures undertaken following the recommendations and suggestions of the 2014 IRRS mission.

The review compared the regulatory framework for safety in France against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and their counterparts from France in the areas covered by the IRRS mission.

The IRRS team consisted of seven senior regulatory experts from seven IAEA Member States and three IAEA staff members.

The IRRS team carried out a review of the measures undertaken following the recommendations and suggestions of the 2014 IRRS mission in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection, enforcement, and the development and content of regulations and guides; emergency preparedness and response; safe transport of radioactive material; radioactive waste management and decommissioning; control of medical exposures; control of radioactive discharges and materials for clearance; environmental monitoring; occupational radiation protection; the interface between nuclear safety and security.

After the initial 2014 IRRS mission, an action plan was developed by ASN based on its findings. The detailed results of this action plan implementation and supporting documentation were provided to the team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics by reviewing the advance reference material and conducted interviews and discussions with ASN, IRSN and MTES staff.

The findings by the IRRS team of 2014 that remain open can be found in Appendix IV.

The new IRRS team findings are summarized in Appendix V.

During the entire course of the preparation and the mission the IRRS team received excellent support and cooperation from the host institution.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS follow-up mission was to conduct a review of the radiation and nuclear safety regulatory framework and activities in France, specifically the measures undertaken following the recommendations and suggestions of the 2014 IRRS mission. The review was carried out by comparison of existing arrangements against the IAEA Safety Standards.

The IRRS review scope included all facilities and activities regulated by ASN.

It is expected that the IRRS mission will facilitate regulatory improvements in France and other Member States from the knowledge gained and experiences shared by ASN, IRRS reviewers, and through the evaluation of the effectiveness of the nuclear and radiation regulatory framework in France and its good practices.

III. BASIS FOR REVIEW

A) Preparatory work and IAEA Review Team

At the request of the Government of France, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) follow-up mission was conducted on 1 June 2017 in Montrouge.

The preparatory meeting was carried out by the appointed Team Leader, Mr Bill Dean, Deputy Team Leader, Ms Ann McGarry and the IAEA representatives, Mr Tim Kobetz and Mr Ronald Pacheco. The French team was led by the ASN Chairman and President, Pierre-Franck Chevet.

During the meeting, the representatives of France provided the IRRS mission preparatory team with an overview on the progress made in response to the 2014 IRRS mission recommendations and suggestions.

The preparatory meeting participants agreed that the scope of the follow-up mission will be the same as the 2014 IRRS mission. This was followed by a discussion on the work plan for the implementation of the IRRS follow-up mission in France from 2 to 9 October 2017. The proposed IRRS team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer identification, lodging and transportation arrangements were also addressed.

The France Liaison Officer for the preparatory meeting and the IRRS follow-up mission was Mr Ambroise Pascal, Head of Cabinet, Office of the Director General, ASN.

ASN provided the IAEA and the IRRS team with the advance reference material for the review in July 2017. In preparation for the mission, the IRRS team conducted a review of the advance reference material and provided their initial review comments to the IAEA Team Coordinator prior to the commencement of the mission.

B) Reference for the review

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

C) Conduct of the review

An initial IRRS team meeting was conducted on Sunday, 1 October 2017, in Montrouge by the IRRS Team Leader and the IAEA Team Coordinator to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. They also presented the agenda for the mission.

The France Liaison Officer was represented at the initial IRRS team meeting so that logistical arrangements planned for the mission could be addressed.

The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 2 October 2017, with the participation of senior management and staff of ASN. Opening remarks were made by ASN Chairman and President, Pierre-Franck Chevet, and Mr Bill Dean, IRRS Team Leader. Mr Olivier Gupta, Director General, ASN, gave an overview of the major regulatory changes in nuclear and radiation safety since 2014.

During the mission, a review was conducted for all the review areas with the objective of providing France with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, interviews and discussions.

The IRRS team performed its activities based on the mission programme given in Appendix II.

The IRRS exit meeting was held on Monday, 9 October 2017. The opening remarks at the exit meeting were presented by Mr Pierre-Franck Chevet and were followed by the presentation of the results of the mission by the IRRS Team Leader, Mr Bill Dean. Closing remarks were made by Mr Greg Rzentkowski, Director, Division of Nuclear Installation Safety.

An IAEA press release was issued at the end of the mission.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

- S1** **Suggestion:** The Government should consider ensuring that all elements of policy and strategy for safety identified in GSR Part 1, are uniformly included in the French legislation at the appropriate level, particularly the fundamental safety objective and the fundamental safety principles should be addressed.

Changes since the initial IRRS mission

Suggestion 1: The fundamental safety objective to protect people from the harmful effects of ionizing radiation is addressed in articles L. 591-1 and L. 591-4 of the Environment Code.

On the 10th February 2016, the Government issued a new Ordinance (2016-128) that amended certain articles of the Environment Code and Public Health Code. When considered with the existing Labour Code, these three codes now incorporate the fundamental safety objective and all ten of the fundamental safety principles set out in SF-1.

Three further decrees are in preparation and due for publication in early 2018. The issuing of these decrees will consolidate many of the existing legal requirements and will also address new measures needed to transpose the Euratom Basic Safety Standards Directive.

Status of the finding in the initial mission

Suggestion 1 (S1) is closed as all elements of policy and strategy for safety identified in GSR Part 1 are included in French legislation at the appropriate level.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

There were no findings in this area in the initial IRRS mission.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

- R1** **Recommendation:** The Government should take the necessary steps in the legislation to provide the regulatory body with the authority for inspections of all activities carried out by all parties with responsibility on safety, without any concern related the place they are fulfilled.
- R2** **Recommendation:** The Government should take the appropriate measures to ensure that ASN's safety related decisions cannot be vetoed.

Changes since the initial IRRS mission

Recommendation 1: Ordinance 2016-128 issued on the 10 February 2016 amended Article L. 593-33 of the Environment Code to strengthen ASN's powers with respect to activities carried out at locations other than the operators' premises, including activities carried out by its providers or sub-contractors. The Ordinance also gave ASN's inspectors powers to inspect all "activities that

are important for the protection of health and the environment” regardless of their location and regardless of the party carrying out the activity. As regards medical exposures, Ordinance 2016-128 and a second Ordinance 2017-45 issued on the 19th January 2017 amended the Public Health Code to give ASN's radiation protection inspectors powers to access documents protected by medical confidentiality.

With respect to nuclear installations, ASN's powers of inspection begin when an application for authorization is received. However it also has other means to provide safety opinions that can be exercised in advance of receipt of the application. In particular, ASN can contribute to public debates/consultations with respect to nuclear installations; under Article 6 of the Decree concerning BNIs and the supervision of the transport of radioactive materials with respect to nuclear safety (2007-1557), ASN can provide its opinion on the safety options proposed by a future operator of a nuclear installation; and ASN can publish a formal notice setting out its views. ASN highlighted several examples where it has provided safety opinions in such a manner.

Recommendation 2: The Ministry for the Ecological and Solidary Transition and ASN have further clarified the position with respect to ASN's effective independence and its authority to make independent regulatory judgements and decisions. ASN can take decisions that have legal force without reference to any other entity. Where an ASN resolution impacts multiple installations, it is regarded as a regulation and, as such, it is subject to a so-called homologation process set out in Article L.592-20 of the Environment Code. There are also a small number of instances where an individual resolution of ASN is subject to approval – these are in setting limits on environmental discharges from a facility; in the de-licensing of a basic nuclear installation or in the suspension of operation of a facility. The purpose of this homologation process is to ensure consistency and coherence between the regulatory texts issued by the Government and ASN. Any changes to the original decision proposed by the Ministry must be approved by the ASN Commission. The updated resolution of ASN together with the approval orders are then published in the Official Journal of the French Republic.

In practice, the Government has never vetoed a resolution of ASN, but minor changes have been made to the initial wording of ASN resolutions to ensure coherence with the existing body of legislation.

Status of the finding in the initial mission

Recommendation 1 (R1) is closed as ASN's inspection powers have been strengthened to cover both off-site activities and activities undertaken by providers and sub-contractors.

Recommendation 2 (R2) is closed as ASN is effectively independent and is able to make independent regulatory judgements and decisions, free from any undue influence that might compromise safety.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

There were no findings in this area in the initial IRRS mission.

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

There were no findings in this area in the initial IRRS mission.

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

S2

Suggestion: The Government should ensure that periodic campaigns for recovery of orphan sources are performed and that comprehensive surveillance systems for the detection of orphan sources are provided in all places where such sources are anticipated to be found.

Changes since the initial IRRS mission

Suggestion 2: In France, every sealed source is registered by IRSN (ASN's technical support organization) in the French national register of radioactive sources. All sealed sources must be registered before being delivered to a licensee. The register has been in place for approximately 60 years. Regulations require that the regulatory body receives immediate notification from the licensee in the event of missing, damaged or uncontrolled radioactive sources.

Regulations also place particular requirements on suppliers of radioactive sources to take back sources from licensees at the end of their useful life. In France, sources are assumed to have a useful life of ten years. When this period has elapsed, licensees must either return the source to the supplier or apply to the regulatory body for an extension. In practice, most sources are returned to the supplier. Suppliers must report quarterly to IRSN on the sources they have supplied and the sources taken back in the previous period. Other opportunities to check that the register is up to date include the requirement to have a form stamped by IRSN before sources are transferred; the requirement to submit an annual inventory to ASN; the requirement to notify all sources imported and exported and to notify ASN of disposals to ANDRA. A licensee's inventory of sealed radioactive sources is also checked by ASN during inspections.

If, in spite of the controls in place, an orphan source is found, ANDRA is responsible for its retrieval and receives a specific budget for this purpose. From time to time, suppliers of sources organize initiatives for the recovery of legacy sources. During this follow-up mission, the IRRS Review Team gained a more in-depth understanding of the full range of measures in France with respect to orphan sources. Given the comprehensive arrangements in place for many years for the control and tracking of sources throughout their lifetime, periodic campaigns for the recovery of orphan sources do not appear to be warranted.

At present, under legislation, portal detectors for radioactivity are installed at the entrance and/or exit to landfills and to some facilities receiving metal waste, including scrap yards and incinerators. Under a new decree to be published in early 2018 to transpose the Euratom Basic Safety Standards Directive, it will also become mandatory for such radiation detection systems to be installed before the end of 2020 at other places where orphan sources may be discovered including the main ports and airports.

Status of the finding in the initial mission

Suggestion 2 (S2) is closed as France has comprehensive arrangements in place for the tracking of sources throughout their lifetime and for the detection and management of orphan sources.

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

There were no findings in this area in the initial IRRS mission.

1.8. COMPETENCE FOR SAFETY

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

R3 **Recommendation:** The Government should provide legal basis for building and maintaining technical competence of all parties involved in Nuclear Safety and/or Radiation Protection.

Changes since the initial IRRS mission

Recommendation 3: Under the Act on energy transition for green growth (TECV Act) and the associated ordinance of the 10th February 2016, France implemented the provisions of the Euratom Directive on Nuclear Safety. In particular, articles of the ordinance taken together with existing legislation, set out the requirements for competence and experience of the licence holders for nuclear installations. There are also similar requirements for sub-contractors. These requirements on the operators are monitored by ASN.

For ASN itself the competency requirements for Commissioners are set out in law. Separately, ASN has set out binding requirements for the competence of its staff in its internal resolution of October 2010. There is a project ongoing to update this resolution. Similarly, a decree published in March 2016 set out the competence required of IRSN staff.

For other users of radioactive sources in the industrial, research and medical fields, there are general provisions concerning education and training in nuclear and radiation safety set out in the Labour and Public Health Codes, as well as various specific provisions in underpinning resolutions and ordinances. In particular, an ordinance published in January 2017 sets out the education and training requirements in radiation safety for medical physicists.

The Strategic Committee for the Nuclear Sector (CSFN) with a broad membership across the industry has worked to develop a concerted approach to the development and maintenance of competence in the sector. Similarly, work on the National Strategy for Research in Energy (SNRE) has focused on developing skills and competence in the research area.

Status of the finding in the initial mission

Recommendation 3 (R3) is closed as France and ASN now have a comprehensive system in place that provides a sound legal basis for building and maintaining the technical competence of operators, the regulatory body, the TSO and users of radioactive materials in industry, medicine and research.

1.9. PROVISION OF TECHNICAL SERVICES

There were no findings in this area in the initial IRRS mission.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

There were no findings in this area in the initial IRRS mission.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

There were no findings in this area in the initial IRRS mission.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

2014 MISSION RECOMMENDATIONS, SUGGESTIONS	
R4	Recommendation: The Government and ASN should explore new ways to ensure that the human and financial resources needed for effective regulation of nuclear and radiation safety are sustained into the future as ASN's workload increases.
S3	Suggestion: ASN should consider reviewing its system for delegating regulatory powers to ensure (1) that the system contains sufficient measures to provide assurance that these powers are being exercised in accordance with Commission expectations and (2) that the balance between the decision-making responsibilities of the HQ and regions is optimal.

Changes since the initial IRRS mission

Recommendation 4: The financial and human resources of ASN and IRSN are established by the State budget. For the 2015-2017 Budget Bill, ASN considered that 125 positions would need to be created by end of 2017. At the end of 2014, 30 additional positions (10 per year) were granted which only partly reflects the anticipated increase in workload. The initial IRRS mission 2014 noted that, if not carefully managed, the shortfall in resources could have a negative impact on the effectiveness of ASN's future regulation.

In 2015, ASN, at the request of the government, performed a more detailed analysis of the resource needs for 2015-2020 that was reflected in the Budget Bill for the 2017. Based on this analysis, the Government granted ASN and IRSN additional resources for 2017 (20 positions at the ASN). However, this still did not fully meet the request. Therefore, ASN and IRSN are continuing the budget discussions with the government for 2018.

For the next budget cycle, ASN issued a new opinion concerning the budget for the regulation of nuclear safety and radiation protection in France. In this opinion, ASN requests the recruitment of an additional 15 FTE for 2018-2020 (5 per year). At the same time, ASN reiterated its request for reform of the financing of its budget to be based partly on the state budget and partly on an annual fee from the licensees.

In addition, ASN has continued to improve its organization to be more efficient by making use of a more graded approach. For example, to better utilize its resources, ASN has categorised nuclear installations into three safety categories based on several criteria (thermal power, activity...) and is finalising regulatory resolutions specifying the scope of declaration, registration and authorisation regimes in the area of use of radiation sources (see also R7), but also another resolution to clarify the approval system of BNI modifications.

Suggestion 3: ASN has revised its system for delegating regulatory signing authority. In 2016-2017 they updated the roles and responsibilities of each hierarchical level and the delegation of signing authority was adjusted, in particular according to the categorisation of BNIs. In the revision of the system for BNI modifications, the regional division heads were delegated the signature authority for resolutions concerning authorisation of temporary measures during plant modifications if they do not include any additional requirements. Delegation of signing authority

was also extended to the office heads and unit heads for small-scale nuclear activities and to the unit heads for some specific topics related to BNIs.

Status of the finding in the initial mission

Recommendation 4 (R4) remains open. Even though the budget decisions increased the number of staff in both ASN and IRSN for the period 2015-2017, ASN remains concerned by the lower than requested financial and human resources as budgeted by the State. ASN has significantly improved its analysis methodology for the resource planning and is currently also improving the efficiency of the organization by further developing the graded approach methodologies.

Suggestion 3 (S3) is closed. The system for delegating regulatory powers and ASN rules about the missions of different hierarchical levels were revised in 2016-2017.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

There were no findings in this area in the initial IRRS mission.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

S4	Suggestion: The regulatory body should consider developing more formalised procedures for long-term staff succession and competency planning. The regulatory body should also consider developing a more formalised tool for competence management.
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Changes since the initial IRRS mission

Suggestion 4: Since the initial IRRS mission, ASN has further developed its existing Human Resources information tools to improve the long-term staff succession and competency planning and competence management functions. ASN has plans to procure a new HR tool combining all the existing information. The new system would enable easier access to the information and provide a better overall picture of turnover and competency management. ASN has contracted a specialised company to assist them in preparation of requirements specifications for a new HR support tool. The plan is to implement the tool in two steps during 2018-2019. ASN has also organized more formalised internal discussions about human resources including staff succession and competency planning. ASN has also recruited a new Deputy to the head of the Office of Administration, whose focus is HR management.

Status of the finding in the initial mission

Suggestion 4 (S4) is closed on the basis of progress made and confidence in the effective completion. ASN has a strong management commitment and continues to develop further its HR information system and is planning to implement a new integrated system in 2018-2019.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

There were no findings in this area in the initial IRRS mission.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There were no findings in this area in the initial IRRS mission.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

There were no findings in this area in the initial IRRS mission.

3.7. SAFETY RELATED RECORDS

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

S5 **Suggestion:** The regulatory body should consider reviewing the current framework to ensure that common standards for the tracking of licensees' commitments and ASN follow-up actions are met throughout ASN's offices.

Changes since the initial IRRS mission

Suggestion 5: In late 2014, ASN published a new procedure for the follow-up of requests and commitments. The procedure covers requests and commitments initiated from: ASN's inspections, ASN's analyses of licensees' responses, significant events, authorisations and enforcement measures. The procedure defines an example for the follow-up table format. Each ASN regional division currently has their own follow-up tables based on the facilities supervised in their region. ASN has plans to continue the work by developing a common national level tool for all of ASN.

Status of the finding in the initial mission

Suggestion 5 (S5) is closed as ASN has published a new procedure for the follow-up of requests and commitments which provides an example for the follow-up table format. Tables have been implemented in the regional divisions.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

There were no findings in this area in the initial IRRS mission.

Policy Discussion 1

Human and financial resources related to upcoming challenges

The purpose of this policy discussion was for the IRRS team to provide insights to ASN on how to ensure that it has access to, maintains, and efficiently uses the necessary human and financial resources to provide adequate oversight of the activities that it regulates.

Since 2014, with the support of the Government, ASN and IRSN have obtained additional human and financial resources from the Parliament. Since 2014, ASN has been allocated 50 new positions. ASN is concerned that resources still are not sufficient to address the unprecedented safety challenges it will continue to face.

In 2017, ASN requests the recruitment of an additional 15 FTE for the 2018-2020 three-year period, corresponding to 5 FTE each year. This assessment takes into account delays regarding some facilities and new needs in response to the discovery of irregularities in the Areva NP Creusot Forge plant. ASN will review its needs in the light of the future budgetary decisions.

The IRRS team acknowledged the challenges faced by ASN and the efforts made to reinforce the graded approach while at the same time establishing new positions. Due to the uncertainties associated with regulating the nuclear industry, it is often difficult to anticipate the future resource requirements of the regulatory body. The IRRS team acknowledged that the people doing the work know best about what is necessary to conduct their work on both a short and long-term basis. The

IRRS team suggested that ASN extend the use of bottom-up approaches and the involvement of the staff to grade the priority of activities and the effort required to perform the activities. ASN could consider polling the staff through questionnaires and interviews to identify improvements for efficiency and incorporation into its plans to implement the efficiencies using a graded approach. An investment is required to implement improvements through innovative methods such as IT solutions and improved resource management tools.

The IRRS team noted that it is difficult to eliminate certain areas of work (e.g., research activities) and that ASN is considering what activities it can reduce or take longer to complete with limited resources (e.g., inspection and licensing activities). The team also noted that French civil servants staffing policies encourage quicker staff turnover and that the expeditious training of people should be a priority.

The IRRS team highlighted that ASN management needs to communicate with the staff in a timely and efficient manner to demonstrate how the staff's work contributes to the overall mission of the agency. These communications are particularly important when efficiency initiatives or budget decisions could lead to reallocate or even reduce staffing levels in the organization.

In addition, the IRRS team noted that ASN has sought efficiencies on financial resources. The IRRS team acknowledged the difficulty of finding the right balance in terms of financing a nuclear safety authority, between receiving funding from operators at the risk of appearing dependent on them and funding from the state budget with the risk of inadequate funding.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

2014 MISSION RECOMMENDATIONS, SUGGESTIONS	
R5	Recommendation: The ASN management system should be completed and fully implemented, in an integrated manner, for all processes needed to deliver ASN's mandate. A systematic analysis for identifying the required processes should be conducted, taking into considerations all the relevant requirements.
S6	Suggestion: ASN should consider updating relevant parts of the management system and associated processes to ensure the management system promotes and supports a strong safety culture in the regulatory body.

Changes since the initial IRRS mission

Recommendation 5: ASN's management system includes 12 key processes divided into management, core and support processes. ASN's management system has been further developed since 2014 and now seems comprehensive. ASN has published several new procedures since the initial IRRS mission especially related to the authorisation process. In addition, common procedures with ASN and IRSN are now formally included in the system. Some of the procedures are still under development (for example the procedure concerning PSRs of NPPs, see S8). Management system documents are available in an electronic format and can be accessed by any ASN staff member on the intranet. The quality policy statement is being updated to explicitly present ASN's mission, values and the two main management system objectives: improving nuclear and radiation safety and improving the efficiency and consistency of ASN's actions.

Suggestion 6: ASN is drafting two new policy documents incorporating the aspects of safety culture: the first on oversight policy and the second on revised quality policy statement. In addition, ASN is drafting a collective commitment document linking the ASN values to the safety culture principles. ASN organised 18 internal staff seminars to discuss ASN oversight, including several safety culture aspects. ASN also used an external human factors expert to carry out an internal survey about the staff commitment and the culture of the organization. Another enquiry was lead with external counterparts to get some regulatory experience from them. The results from the seminars and from the enquiries were used when drafting the policy documents and the collective commitment. ASN considers that the draft policy documents are in line with the IAEA safety culture principles.

In 2018, ASN plans to check the consistency of management system documents with the new policy documents and to update them as necessary. ASN also plans to include safety culture principles in the inspector training programmes. ASN has not yet made plans for carrying out safety culture self-assessments which they could use to further develop their safety culture.

Status of the finding in the initial mission

Recommendation 5 (R5) closed on the basis of progress made and confidence in the effective completion. Since the initial IRRS mission in 2014, ASN has continued to develop the structure of its management system and published many new procedures. The IRRS team found that the structure of the management system is comprehensive, however, some procedures still need to be published and the revised quality policy statement needs to be finalised.

Suggestion 6 (S6) remains open. ASN is finalising two new policy statements and a collective commitment document incorporating the aspects of safety culture. ASN has plans to review its MS documents and to include safety culture principles in the inspectors' training programmes. ASN has not yet made plans for carrying out safety culture self-assessments which ASN could use to further develop their safety culture.

4.2. MANAGEMENT RESPONSIBILITY

There were no findings in this area in the initial IRRS mission.

4.3. RESOURCE MANAGEMENT

There were no findings in this area in the initial IRRS mission.

4.4. PROCESS IMPLEMENTATION

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

R6 **Recommendation:** ASN should carry out a systematic and comprehensive audit of IRSN's review and assessment activities against ASN's MS requirements.

Changes since the initial IRRS mission

Recommendation 6: ASN conducted an audit of the ASN-IRSN agreement and its appendices in 2016. The audit team was led by an external expert and the rest of the team members were from ASN. The audit included a review of human resources and a review of the agreements and internal procedures through examination of some selected examples. The examples included several different types of safety assessments prepared by IRSN concerning nuclear power plants. Several recommendations and suggestions were given to both IRSN and ASN but the audit didn't reveal any shortcomings or significant deviations. The recommendations and suggestions have been discussed in the common meetings but there is not yet a single action plan for the follow-up.

ASN and IRSN have plans to continue the audit programme. However, the auditing interval has not been established. Both ASN and IRSN determined that it would be beneficial to have both ASN and IRSN staff members on the audit team in future since the recommendations and suggestions are given to the both organisations.

Status of the finding in the initial mission

Recommendation 6 (R6) is closed as the audit of IRSN's review and assessment activities was conducted by ASN in 2016.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

There were no findings in this area in the initial IRRS mission.

5. AUTHORIZATION

5.1. GENERIC ISSUES

There were no findings in this area in the initial IRRS mission.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

There were no findings in this area in the initial IRRS mission.

5.3. AUTHORIZATION OF RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

R7 **Recommendation:** The regulatory body should ensure a more consistent implementation of the graded approach for the authorization of radiation sources and facilities.

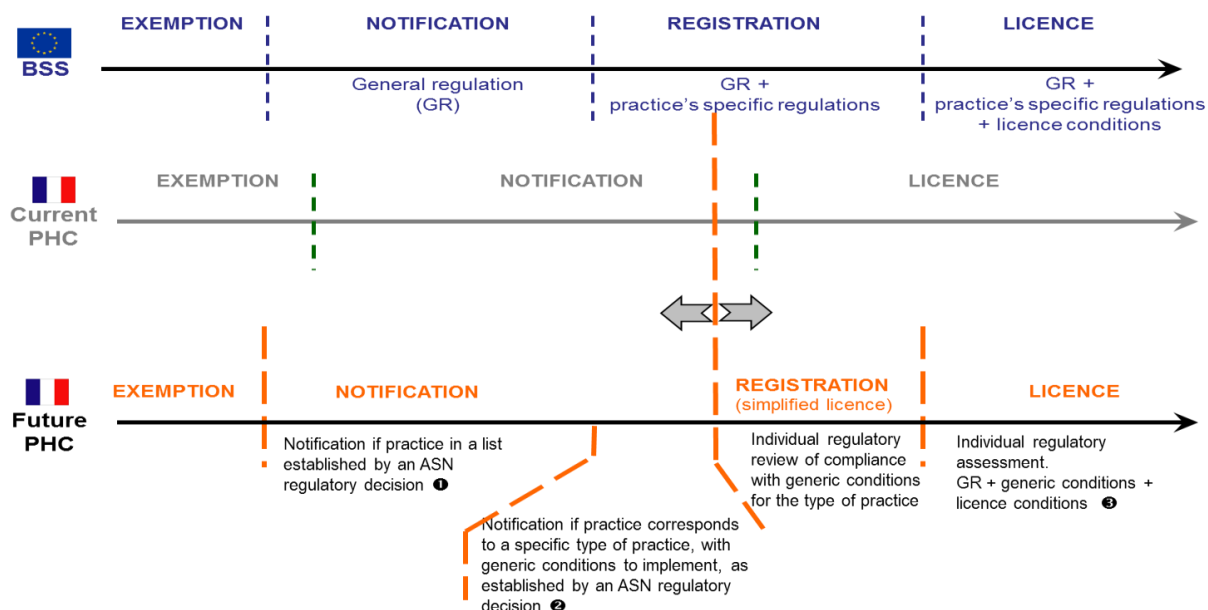
S7 **Suggestion:** ASN should consider extending the practice of issuing the authorization for radiation sources and facilities to the appropriate legal entity to ensure that the holder of the authorization can assume the full responsibility of their activities.

R8 **Recommendation:** The Government should clearly define in the regulatory framework the responsibilities of ASN with regard to the national sealed sources register.

Changes since the initial IRRS mission

Recommendation 7: The legislative part of the Public Health Code (PHC) has been updated to reflect the European Basic Safety Standard and its regulatory part is being updated. It will come into effect in early 2018 after the on-going review by the Council of State. This will introduce an additional category of authorization known as “Registration”.

This will increase the number of different types of authorization from 2 to 3 which is consistent with the European Basic Safety Standard as shown in the schematic below:



A significant number of activities which are currently licensed will fall under the registration or notification scheme. The activities which require notification will not have a time limitation on their validity.

The registration scheme will be a simplified licensing process which requires a simpler application with less supporting documentation.

These proposals are supported by the Regional Divisions of ASN who undertake the majority of authorizations within ASN.

The IRRS team was provided the proposed graded approach to authorization, including the duration of the authorization. It was noted that the proposed licence duration for the majority of medical practices, including external radiotherapy and brachytherapy, should be 10 years. This proposal does not appear to take account of the risk of practices changing during this relatively long time period. In addition, the proposed duration for registration and licensing of some medical practices should be both 10 years which does not appear to be consistent with the graded approach. Practically, in case of significant change of the practice, the license or the registration will be updated.

Suggestion 7: The updated PHC will come into effect in early 2018 which will introduce an additional category of authorization as detailed in Recommendation 7 above.

Following this update to the PHC, ASN will progressively reissue authorizations to a legal entity rather than a person as they become due for renewal e.g., on licence expiry, licence amendment etc.

It is estimated that this will affect approximately 10 000 authorizations which will be reissued over a period of 3-5 years.

Recommendation 8: The updated PHC will come into effect in early 2018, which defines the framework for registering and tracking radioactive sources. The ASN resolution 2015-DC-0521 which entered into force in January 2016 is foreseen in the updated PHC and details the process and actions that have to be taken to register a source in the national register. As has been described in Recommendation 7, the draft decree has been approved in principle by the Government but still requires review by the Council of State before it can be issued in early 2018.

The ASN resolution 2015-DC-0521 demonstrates the graded approach where the requirements for registering high activity sources are increased, and exempt sources do not require registration.

Although the national sealed source register contains details of all sealed sources, it only contains limited information on radiation generators. However, there is a requirement in the Labour Code (R.4451-38) for ASN licence holders to submit an annual inventory of all their sources, including radiation generators, to IRSN which is also available to ASN.

Status of the finding in the initial mission

Recommendation 7 (R7) is closed on the basis of progress made and confidence in the effective completion as the Government will issue an updated PHC in early 2018. The PHC will introduce an additional category of authorization known as “Registration” allowing a more graded approach to authorization of radiation sources and facilities. The draft decree has been approved in principle by Government, but still requires the ongoing review by the Council of State to be completed before it can be issued.

Suggestion 7 (S7) is closed on the basis of progress made and confidence in the effective completion. When the updated PHC is issued in early 2018 with the additional category of authorization, ASN will progressively reissue authorizations to legal entities rather than physical persons which is expected to be completed in a time period of 3-5 years, covering approximately 10 000 authorizations.

Recommendation 8 (R8) is closed as ASN issued a new resolution 2015-DC-0521 in January 2016 which details the processes which need to be undertaken to register a sealed source in the national register. The updated PHC which will be issued in early 2018 references this ASN resolution and clearly defines the framework for registering and tracking radioactive sources, including the responsibilities of both ASN and IRSN.

5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

5.8. AUTHORIZATION OF TRANSPORT ACTIVITIES

There were no findings in this area in the initial IRRS mission.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

There were no findings in this area in the initial IRRS mission.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

S8 **Suggestion:** The regulatory body should consider issuing internal guidance on the review and assessment activities to be undertaken in the frame of the periodic safety reviews covering all safety factors of SSG-25.

Changes since the initial IRRS mission

Suggestion 8: The IRRS team was informed that ASN is currently working on a resolution “Periodic Safety Review” related to all basic nuclear installations. The consultation of the public which is mandatory for an ASN resolution is already completed. Developing the resolution ASN took the relevant aspects of SSG-25 into account. ASN presented the related document (Orientation and Justification file) to the IRRS Team. ASN plans to publish the resolution in 2017. The IRRS team was informed that ASN plans to issue internal guidance for NPPs after the publication of the regulatory decision in 2017. ASN's plan to proceed seems reasonable to the IRRS team.

An internal guidance on periodic safety review (PSR)-activities related to non NPP-facilities was issued by ASN at the end of 2015. The IRRS team was informed that ASN plans to use the feedback from the application of this guide to write the guidance for NPPs.

For PSR currently under review ASN formalized the areas to be covered in the PSR in a public letter dated April 2016.

Status of the finding in the initial mission

Suggestion 8 (S8) remains open. ASN is currently working on a resolution “Periodic Safety Review” related to all basic nuclear installations. In developing this resolution, ASN took the relevant aspects of SSG-25 into account. This resolution is not yet published.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES

There were no findings in this area in the initial IRRS mission.

6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

6.8. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

There were no findings in this area in the initial IRRS mission.

7. INSPECTION

7.1. GENERIC ISSUES

2014 MISSION RECOMMENDATIONS, SUGGESTIONS	
S9	Suggestion: ASN should consider developing a set of internal guidance criteria for initiation of reactive inspections.

Changes since the initial IRRS mission

Suggestion 9: ASN performs regularly reactive inspections. The decision to perform such an inspection was taken on a case by case basis. Following the IRRS mission 2014 ASN has evaluated their experience from past reactive inspections. A draft procedure for initiating reactive inspections was presented to the IRRS team. The draft contains several criteria (mandatory and non-mandatory) to take into consideration in making a decision to perform a reactive inspection. The criteria presented to the IRRS team (e.g., INES-classification, quality of the information reported to ASN and generic aspects of the event) seem reasonable. The validation process for this draft is in the final stage.

Status of the finding in the initial mission

Suggestion 9 (S9) is closed on the basis of progress made and confidence in the effective completion. ASN has evaluated their experience from past reactive inspections and developed a draft procedure and the criteria for initiating reactive inspections. The validation process for this draft is in the final stage.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

2014 MISSION RECOMMENDATIONS, SUGGESTIONS	
S10	Suggestion: ASN should formally analyse and, if needed, supplement the missing inspection topics in the inspection programme, to ensure that all areas of ASN regulatory responsibility are covered.
S11	Suggestion: ASN should consider completing its internal documents to provide guidance for all inspection topics and update existing inspection guides.
S12	Suggestion: ASN should consider finishing inspection strategy for NPPs' commissioning stage. Inspection programme including clearly defined topics should be developed well in advance before commissioning activities are started.

Changes since the initial IRRS mission

Suggestion 10: ASN has verified that all areas listed in the Appendix of the GS-G-1.3 were covered by their inspection programmes, either through periodic inspections or specific approaches (e.g., for the commissioning stage the guide INS-ASN-000420 for NPP (EPR)). ASN presented a related correspondence table as part of the ARM. The examples reviewed by the IRRS team did not indicate any areas of ASN responsibilities which are not covered.

The IRRS team notes that the starting point for the licensing process in France is the request for creation of a nuclear installation. For all activities prior to this request ASN has no legal mandate to carry out inspections nor decision authority.

Suggestion 11: ASN has reviewed all inspection procedures and related guidance documents since the IRRS mission in 2014. In addition ASN has established a process to periodically review the needs for new inspection guides or revise existing guides. Senior management receives a report of the status of the inspection guides every six months. The ASN process seems reasonable to the IRRS team. ASN presented a summary of the status of all guides related to inspection procedures to the IRRS team. For the following three areas no guides are currently available: particle accelerator, polluted sites and use of sealed and unsealed sources for research activities. ASN has developed a schedule to develop the missing guides.

Suggestion 12: ASN has established an inspection strategy for the commissioning of the project of Flamanville 3 EPR reactor since the IRRS mission in 2014. ASN took into account the relevant IAEA Safety Requirements and Guides. A guide for site inspections related to commissioning tests (CT) was published by ASN in 2015, which provides guidance for the preparation and the performance of the inspections. The guide was presented to the IRRS team. The licensee provides ASN information about the proposed dates for the CT 15 days before their performance. ASN will inspect the CT on the basis of the advice of their technical consultant IRSN. ASN presented a list of performed inspections for CT in Flamanville 3 to the IRRS team.

Status of the finding in the initial mission

Suggestion 10 (S10) is closed as ASN has prepared a cross reference table showing that all areas of ASN's responsibility were covered by their inspection activities.

Suggestion 11 (S11) is closed on the basis of progress made and confidence in the effective completion. ASN has set up an adequate process to ensure a periodic review of all inspection guides and has used the process to update some guides. A few inspection areas are not yet covered by inspection guides.

Suggestion 12 (S12) is closed as ASN has implemented an inspection strategy for the commissioning of NNPs' commissioning state and the related inspection programme is in place.

7.3. INSPECTION OF RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

7.4. INSPECTION OF FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

7.6. INSPECTION OF RADIATION SOURCES FACILITIES

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

- S13** **Suggestion:** ASN should consider harmonizing inspection activities between the medical and non-medical areas in accordance with a graded approach for all sources, including low risk sources.

Changes since the initial IRRS mission

Suggestion 13: ASN established a task force between September 2016 and April 2017 to examine the regulatory framework and the oversight activities of both medical and non-medical sources, especially inspection activities.

In addition, as mentioned in Recommendation 7, the upcoming PHC will result in a more graded approach to authorization which will in turn affect the inspection programs for both sectors. For example, an increased number of practices will only require to be notified which will not require planned inspections.

This new graded approach will apply to both medical and non-medical sectors, resulting in more consistent or harmonized inspection programs. In order to make the most efficient use of its resources, ASN reviews its national priorities for its inspection programs each year.

ASN is currently developing a core or minimum set of areas for each type of inspection for medical and non-medical inspections, and it is expected that this should be completed by end of 2017. This will result in a more consistent approach to inspections in both sectors, and increase the flexibility available to inspectors to customise the duration and scope of inspections depending on what is discovered at the time of the inspection.

ASN presented the documents framing the inspection plans for 2018 to the IRRS team for both the medical and non-medical sectors. These plans identified national priorities and inspection themes for both sectors demonstrating a risk-informed consistent approach.

Status of the finding in the initial mission

Suggestion 13 (S13) is closed on the basis of progress made and confidence in the effective completion as ASN has updated the approach to inspection activities in medical and non-medical radiation practices, including a graded approach with inspection frequency based on risk of the activity. However, work is still ongoing in this area, including the development of a core or minimum set of inspection requirements which is due to be completed by the end of 2017.

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

7.8. INSPECTION OF TRANSPORT ACTIVITIES

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

S14 **Suggestion:** ASN should consider developing a more effective training to address the limited number of transportation inspectors and the turnover in the Divisions.

Changes since the initial IRRS mission

Suggestion 14: ASN has developed an online training package which can be undertaken throughout the year.

On completing the online training package, the trainee inspector needs to undertake a mandatory examination which certifies the inspector as competent to undertake transport inspections. The training program also has management oversight to ensure the quality of the program.

The program is modular and can be undertaken at different levels so that those requiring a general overview of transport inspections can undertake the training at a less detailed level. The modular program can also be used for refresher training.

As a result of the online training, ASN is now able to designate transport inspectors throughout the year, therefore facilitating the conduct of transport inspections in a more timely fashion compared to the situation in 2014. Currently there are at least two qualified transport inspectors in each of the Regional Divisions. It was also noted that Transport and Sources Department (DTS) at ASN undertakes around 60 percent of the total transport inspections and can provide additional resources to the regions when needed.

Finally, ASN still delivers a training program once per year which allows more interaction between transport inspectors with varying degrees of experience and provides additional quality assurance to the program.

Status of the finding in the initial mission

Suggestion 14 (S14) is closed as ASN has introduced an online training package for transport inspectors which has allowed ASN to address the deficit in the number of competent transport inspectors observed in 2014.

Policy Discussion 2

Control of supply chain and counterfeit, fraudulent and suspect items (CFSI)

In recent years nuclear facilities around the world have been impacted by several procurement related events. In particular, CFSI issues are a growing concern for the nuclear industry and the safety regulatory authorities. Several cases have occurred in France since 2015, including a major one involving components forged by the Areva NP Creusot Forge factory.

The construction of the Flamanville Unit 3 EPR reactor has also shown that developing a robust supply chain is a challenge for licensees and vendors. This is a concern for ASN as EDF is engaging a major plant life extension program for its reactor fleet.

Before 2016 ASN did not have the authority to directly inspect suppliers. They only had the authority to assess how the licensee oversaw its suppliers. Through recent legislative developments, ASN is now able to inspect suppliers directly on site. Now ASN is in the process

of establishing and implementing an effective supply chain oversight strategy. In addition, in 2017 ASN began exploring how to better identify problems with CSFI.

The IRRS team noted that it is essential to plan resources for the inspection of vendors, through a graded approach. Regulatory bodies need to emphasize to licensees that the responsibility for the oversight of suppliers and vendors lies with the licensees. Licensees are responsible to ensure that the suppliers and vendors are providing products and services in accordance with the required quality assurance standards and that the safety related requirements are communicated through the supply chain. The regulatory bodies should confirm that the licensee is meeting this obligation.

The team also confirmed that regulatory bodies must have the legal authority to inspect vendors and suppliers. All contractors must understand that they can be inspected at any time. ASN should continue to work with international organizations such as the IAEA and NEA and with other countries to promote the exchange of information regarding the vendor inspection findings. This is particularly important as more and more vendors begin to provide products and services to the nuclear industry without previous experience in the industry.

Regarding developing the ability to identify CSFI the IRRS team agreed with ASN that it is very difficult to identify the counterfeit equipment and components and the falsification of records and human behaviour cannot be predicted. The problem is not only for mechanical components but covers a wide area including the digital, electrical and computer components (including software) which can lead to cyber security issues. In addition, the regulatory body require sufficient enforcement tools (e.g., significant civil penalties and the possibility of additional legal action).

Lastly, the IRRS team provided its views on the best methods for communicating the CSFI issues to interested parties. The team agreed with ASN that there are significant legal challenges of when and how CSFI issues can be introduced to the public. The IRRS team offered that ASN will need to closely coordinate with enforcement officials before communicating with interested parties.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

- S15** **Suggestion:** The Government should consider revision of legal basis for ASN enforcement actions (both penal and administrative sanctions), especially to allow for more precise gradation of sanctions.

Changes since the initial IRRS mission

Suggestion 15: The Government and the Parliament have revised the legal basis for administrative actions for ASN in 2015 and 2016. ASN has received additional powers by law (Environmental Code) for administrative sanctions. ASN can now decide on daily fines an operator has to pay as long as a violation of a requirement exists. In addition, a sanction committee, composed of ASN and other legal entities, will be put in place. The members of this committee have the power to decide on administrative fines (up to € 10m). The sanction committee has not been established yet. The IRRS team was informed that the related decree is currently at the final elaboration stage. The IRRS team recognizes that the additional power given to ASN allows ASN an effective and more precise gradation of sanctions.

Regarding penal sanctions there has been no change. In the French Constitution only the judiciary has penal decision powers. Therefore, this aspect of the S15 is not applicable.

Status of the finding in the initial mission

Suggestion 15 (S15) is closed as the legal basis for ASN enforcement actions has been revised. ASN has received additional powers by law.

8.2. ENFORCEMENT IMPLEMENTATIONS

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

- R9** **Recommendation:** ASN should revise basic documents related to enforcement (ASN/SAN/01, ASN/SAN/02 and related policy document) establishing more detailed criteria for enforcement actions.

Changes since the initial IRRS mission

Recommendation 9: ASN has replaced the document ASN/SAN/02 in 2015 by the documents ASN/SAN/120 and ASN/SAN/122. Both documents were presented to the IRRS team. They contain the procedure determining enforcement measures and sanctions, the handling of significant events and the monitoring process for enforcement measures. The Appendix of ASN/SAN/120 gives guidance for the evaluation of the seriousness of the deviation and the grading of the measures. Both documents give the inspectors detailed guidance and rapid access to the measures that can be taken into consideration for each deviation. In addition, SAN/122 contains a list of examples for enforcement measures taken in comparable situations. The IRRS team recognises that with these two documents ASN has established detailed and applicable criteria for enforcement actions.

The IRRS team was informed that the policy strategy document for enforcement is currently under revision. A draft was presented to the IRRS team. ASN plans to issue the new strategy at the end of 2017. The document ASN/SAN/01, related to methods of enforcement in general is also currently under revision. ASN plans to issue the revised version after issuing the policy strategy.

Status of the finding in the initial mission

Recommendation 9 (R9) is closed on the basis of progress made and confidence in effective completion. ASN has established detailed and applicable criteria for enforcement actions. The inspection strategy and the document related to methods of enforcement in general are currently being revised.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

2014 MISSION RECOMMENDATIONS, SUGGESTIONS	
R10	Recommendation: The regulatory body should complete the project for developing technical resolutions and guides in a timely manner.
S16	Suggestion: The regulatory body should consider further clarifying the graded approach used in the regulations and guides for different facilities and activities.
S17	Suggestion: ASN should consider setting out, in the regulations or guides, explicit criteria related to the analyses of incidents and accidents.
R11	Recommendation: ASN should develop more detailed guidance for the review and renewal of regulations and guides. The guidance should also include regular assessment of the need to renew regulations including updated IAEA safety standards as an initiator for such renewal.

Changes since the initial IRRS mission

Recommendation 10: ASN has now completed 18 of 23 regulatory resolutions (decisions) for BNIs. This accounts for approximately 80 percent of the work (status was approximately 50 percent in 2014). ASN continues to finalise the missing resolutions and regulatory guides, most importantly, those related to periodic safety review, operating rules and the management system of the operators. ASN has implemented about 75 percent of the WENRA reference levels (RLs) in the national regulations. The most recent publications cover RLs related to NPP design and emergency preparedness.

ASN continues to adopt new regulatory decisions for small scale nuclear activities and to revise the regulations resulting from the transposition of the European directive of December 2013 (Basic Safety Standards, BSS). ASN also participates in the drafting of the ministerial orders. ASN has developed a table tracking its compliance with all BSS articles and the schedule for updating the French regulations and guides. Some of the biggest changes are related to radon and radiation safety experts.

Suggestion 16: ASN has a policy that most regulations and guides are applicable to all BNIs. In September 2015, ASN adopted a resolution establishing a classification of BNIs into three safety categories based on several criteria (thermal power, activity, ...). This categorisation has not yet been widely utilised for establishing regulatory requirements based on a graded approach, however, the categorisation has been used in ASN's internal procedures for grading the oversight measures and the signature level (see S3). For example, post-Fukushima actions were prioritised based on the BNI categorisation. ASN is also finalising the draft regulatory guide concerning the management of BNI modifications, where the licensee is required to determine its internal classification for different types of modifications. Until now, ASN has reviewed all the modifications. In the future, ASN expects the number of applications to decrease by 70 percent. ASN has also worked on clarifying the graded approach for the evolution of the regulatory framework for small-scale nuclear activities (see R7) and for enforcement measures (see R9).

Suggestion 17: In the French regulatory approach, the safety objectives for incidents and accidents are set based on intervention levels (e.g., levels initiating evacuation, sheltering and restrictions to food consumption). BNI ministerial order (7 February 2012) also requires the licensees to ensure that the radiological consequences are as low as reasonably achievable (ALARA) in the case of incidents and accidents (not only for normal operation). In November 2015, ASN published a resolution concerning the BNI safety analysis report (SAR), which requires that the SAR defines the criteria for addressing the consequences of incidents and accidents in the light of regulatory requirements. In practice, this means that the licensee is performing the radiological consequence analysis and confirming that the results are well below the intervention levels. The IRRS review team concluded that the actions taken by ASN are sufficient to ensure the fulfilment of the general safety goal in the GSR Part 1 Section 4.62.

Recommendation 11: ASN published an external guide “*Preparation of ASN statutory resolutions and ASN guides*” in October 2016. The guide provides the framework and the process whereby the licensees, manufacturers and other stakeholders are invited to take part in the preparations of the ASN draft resolutions and guides relating to BNIs. The guide also describes how feedback from the stakeholders can be sent to ASN after the resolutions and guides have been in use for a few years. Regulatory experience feedback is collected through formalised evaluation processes and there is also a formalised procedure to seek guidance from the legal office. The legal office also gives feedback to the drafting team when updating resolutions and guides.

The update of ASN’s internal procedure, Note ASN/REG/01, describing the process for developing and updating regulations and guides has been started but it needs to be finalised. ASN’s note ASN/REG/01 states the IAEA Safety Standards that are to be used when developing national resolutions and guides. However, the process to keep national resolutions and guides consistent with the IAEA safety standards as they evolve is not yet formalised. In 2016, ASN developed an informal table covering IAEA safety requirements level documents and the sections responsible to ensure their implementation.

Status of the finding in the initial mission

Recommendation 10 (R10) is closed on the basis of progress made and confidence in the effective completion. ASN has made significant progress since the initial mission by publishing new decisions and guides and have clear plans to finalise the project.

Suggestion 16 (S16) is closed as ASN has published a new resolution establishing a classification of BNIs into three categories. ASN is also finalising a new regulatory guide on management of BNI modifications and the regulations for small-scale nuclear activities clarifying the graded approach by the end of 2017.

Suggestion 17 (S17) is closed as ASN has published a new resolution concerning the BNI safety analysis report. The utilization of the ALARA principle and the requirement for licensees to analyse the radiological consequences and compare them to the intervention levels is sufficient to ensure the fulfilment of the general safety goal in the GSR Part 1.

Recommendation 11 (R11) remains open as an internal procedure describing the process for developing and updating regulations and guides has not been updated since the initial IRRS mission. Although a new external guide was published concerning the participation of the stakeholders in the updating of resolutions and guides, there is no procedure for regular assessment of the need to update the resolutions or guides. In addition, the process to keep national regulations consistent with the IAEA safety standards as they evolve is not yet formalised.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

There were no findings in this area in the initial IRRS mission.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

9.4. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

9.5. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

S18

Suggestion: ASN should consider gaining specific expertise and developing specific safety guides (standard format and content of a safety case, site criteria, etc.) related to a near-/sub-surface disposal facility in a timely manner (depending on the options to be proposed by Andra in 2015).

Changes since the initial IRRS mission

Suggestion 18: Following the 2014 IRRS mission, ASN requested its TSO (IRSN) to review its existing near and sub-surface disposal guidelines. These guidelines are mainly concerned with the siting of a near or sub-surface disposal facility, and were published in 2008. Specifically, ASN requested advice on what aspects of the guidelines required to be updated and also what needed to be added.

IRSN provided the results of its review in June 2017 in its Avis IRSN/2017-00216.

The delays which have occurred in implementing this suggestion were due to competing national priorities to allow IRSN's assessment of the CIGEO deep geological repository project.

ASN and IRSN have decided to form a working group which also includes ANDRA and some waste producers, to develop a new near or sub-surface disposal guide. It is expected that the Terms of Reference and the composition of the Working Group will be finalised before the end of 2017.

With respect to gaining specific expertise as made in the suggestion, ASN has stated that it has appointed a project manager for the development of the guide since the 2014 IRRS mission, and has also recruited several positions in the waste management area.

Status of the finding in the initial mission

Suggestion 18 (S18) remains open. Since the 2014 IRRS mission, no new or updated safety guide on near surface or sub-surface disposal facilities has been produced. A working group of relevant stakeholders is now being established to develop and produce a new or updated guide.

9.6. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES

There were no findings in this area in the initial IRRS mission.

9.7. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

9.8. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

S19 **Suggestion:** ASN should consider completing the process to implement the Public Health Code to require notification by carriers of radioactive material.

Changes since the initial IRRS mission

Suggestion 19: ASN published a resolution in March 2015, 2015-DC-0503, which requires carriers to provide notification of transport of radioactive materials.

This requirement became effective in October 2016 when ASN provided an online portal on its website for carriers to provide notification of transport of radioactive materials, which was demonstrated to the IRRS team.

Status of the finding in the initial mission

Suggestion 19 (S19) is closed as the ASN resolution 2015-DC-0503 which was made in March 2015 and became effective in October 2016, requires carriers to provide notification of transport of radioactive materials.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. GENERAL EPR REGULATORY REQUIREMENTS

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

- R12** **Recommendation:** ASN should encourage a revision of emergency plans to ensure that severe accidents with uncontrolled releases are taken into account in the emergency preparedness and response (EPR) threat/hazard assessment for emergency planning and for the development of a protection strategy. Exercises should also address such scenarios.

Changes since the initial IRRS mission

Recommendation 12: The finding in 2014 was that the onsite threat/hazard assessment or onsite emergency planning basis, was not required to take into account severe accidents with uncontrolled releases, and accordingly only design basis type accidents were generally considered in emergency plans. At the time of the 2014 mission, the requirements for emergency preparedness and response (EPR) were stated in the Decree n°2007-1557 for BNI of 20 November 2007 and in more detail in chapter VII of the ministerial Order about BNIs of 7 February 2012.

Since the 2014 mission, ASN has issued resolution 2015-DC-0532 about Safety Reports, which includes a specific chapter (VIII) related to the onsite emergency planning basis. Article 4.8.1 explicitly requires that accidents beyond the design basis be included in the planning basis. Furthermore, article 4.8.2 requires operators to identify all possible accidents that offsite authorities need to be aware of, and to provide them with the consequences of these accidents to be considered in development of offsite plans.

In addition to the enhanced requirements for onsite emergency planning basis in the safety report, ASN has issued resolution 2017-DC-0592 about emergency preparedness and response. This resolution lays out comprehensive requirements for onsite emergency plans. Although the new resolution makes no direct reference to the magnitude of accidents to be considered (as this is addressed in the revised safety report requirements), it does establish requirements that are in fact required for managing severe accidents. Title VII addresses the need for emergency response facilities and article 7.2 addresses the habitability of the emergency response facilities and, in particular, prolonged releases with requirements for power supply, filtering, air conditioning and supplies of food or water. These are clearly means that would not likely be required for design basis accidents only. These requirements will come into effect on 1 January 2018.

Finally, in addition to the changes in the regulatory framework for licensees and onsite plans, key changes have been made to offsite planning arrangements for severe accidents. As a follow-up to the 2014 update of the national nuclear emergency plan, a ministerial letter was issued with 6 specific actions areas. In particular, prefects are required to enhance offsite plans by: extending the preparedness zone from 10km to 20km, including potassium iodide pre-distribution; introducing a new 5km immediate evacuation zone; and finally introducing default immediate actions on food restrictions. A guidebook on implementing these changes has been developed to assist the prefect in undertaking these changes to offsite plans.

Status of the finding in the initial mission

Recommendation 12 (R12) is closed as a result of the work since 2014 on updating the regulatory framework, the implementation of changes to national offsite planning, and the planned course of action for updating the onsite emergency planning basis in the licensee safety reports.

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

S20	Suggestion: The regulatory body should consider improving the emergency classification system, incorporating a clear graded approach, consistent with (but not necessarily identical to) the guidance provided in GS-R-2.
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Changes since the initial IRRS mission

Suggestion 20: Regulatory requirements have been updated to require that when the operator activates their onsite plan, they notify the prefect and ASN. In ongoing communications with the prefect, the operator indicates the expected timing and magnitude of a possible release. This information is used by the prefect, who infers when the offsite plan should be activated and whether protective actions need to be taken. In addition, the operator can initiate the offsite plan in “reflex mode” in case of an immediate radioactive release.

The 2014 National Plan identifies 3 accident situations labelled 1, 2 and 3 (immediate/short release, immediate/long release, delayed/long release). These situations have suggested actions to be taken by offsite response authorities. By definition, these are in fact all subsets of a General Emergency classification.

ASN interprets the various onsite and offsite activation levels and “converts” this information into an emergency class (Alert, Facility Emergency, Site Area Emergency or General Emergency) for reporting to IAEA.

Status of the finding in the initial mission

Suggestion 20 (S20) is closed on the basis of changes to the regulatory framework and the national nuclear emergency plan.

New observation from the follow-up mission

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The regulatory framework and operator procedures include a system for determining the appropriate level of response both onsite and offsite. However, there is no system for the operator to classify the emergency using pre-established classes consistent with GSR Part 7.*

(1)	BASIS: GSR Part 7 Para. 5.14 states that “ <i>The operating organization of a facility or activity in category I, II, III or IV shall make arrangements for promptly classifying, on the basis of the hazard assessment, a nuclear or radiological emergency warranting protective actions and other response actions to protect workers, emergency workers, members of the public and, as relevant, patients and helpers in an emergency, in accordance with the protection strategy (see Requirement 5). This shall include a system for classifying all types of nuclear or radiological emergency</i> ”
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FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

SF1

Suggestion: The regulatory body should consider developing definitions of emergency classes consistent with those defined in GSR Part 7 and ensure operators classify emergency situations and communicate the emergency class to offsite response authorities.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

S21

Suggestion: ASN should consider developing a methodology to evaluate the performance of licensees during emergency exercises based on an integrated systemic approach to performance evaluation.

Changes since the initial IRRS mission

Suggestion 21: In France, various levels of emergency exercises are undertaken: Major Exercises involving the Government, National Exercises with operator/prefect/IRSN/ASN and finally licensee internal exercises. All these exercises are evaluated and lessons learned are produced in a collaborative manner among all participants. In the case of Major Exercises the SGDSN (Prime Minister Services) produces an after action report, for National Exercises the ASN coordinates the after action report, and finally for licensee internal exercises, a self-evaluation is prepared by the licensee.

ASN performs comprehensive licensee inspections on emergency preparedness and response (EPR), but not during national emergency exercises. ASN inspections focus on program implementation aspects such as document verification, system readiness verification, etc., and in some cases local exercises or simulations. In addition, ASN will use a scenario to have the licensee run a real-time drill of a specific subset of their onsite response plan (for example, alerting and accounting of personnel, muster of response teams, etc.). ASN will also use after action reports from licensee self-evaluations to perform reactive inspections and ASN also stages unannounced inspections with these real-time drills. The full set of EPR inspection activities by ASN is quite comprehensive. However, there is no systematic evaluation of the operators during exercises by ASN.

To complement the existing arrangements ASN has started working with the Office for Nuclear Regulation in England (ONR) on an exercise assessment called Level 1 Demonstration Emergency Exercise. It is part of an ONR monitoring process, which concludes with an inspection report and a letter of feedback to the operator. ONR has a specific evaluation guide whose objectives and success criteria are relatively numerous. These evaluations require an important preparation phase and the synthesis also requires a compilation of the observations during the exercise. The team of evaluators must have the necessary skills for such an assessment.

ASN is considering supplementing the existing system by adopting the ONR's Level 1 Demonstration Emergency Exercise evaluation practice and has included this in their 2018/19 EPR planning as documented in an internal document. An observation of such an exercise in UK took place in June 2017 by 2 ASN inspectors and a working group involving the agents of the territorial divisions and directorates as well as the Security Officer of the ASN will be set up.

Status of the finding in the initial mission

Suggestion 21 (S21) is closed on the basis of progress made and confidence in effective completion as a result of the comprehensiveness of oversight tools available to ASN to assess operator EPR arrangements as well as the documented course of action for implementation of an emergency evaluation inspired by ONR practices.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

S22 **Suggestion:** The ASN should consider including all critical strategic interfaces, including senior government and political officials in some exercises to test the effectiveness of the role of ASN as an advisor to the government during an emergency.

Changes since the initial IRRS mission

Suggestion 22: Major nuclear exercises are organized by the Prime Minister services (SGDSN) every three years, and these include senior staff and Government officials. The coordination and decision-making system used for nuclear emergencies, Centre Inter-Ministeriel de Crise (CIC) is the same as used for all-hazard situations (for example, floods, fires, security incidents, etc). Although political official rarely, if ever, participate in nuclear emergency exercise, they are regularly required to use the CIC for real events. Accordingly, senior government and political officials are kept familiar with the national crisis management and decision making system, which would be used for a nuclear emergency.

The most recent Major Exercise was held in 2016. During this exercise, ASN senior leadership participated in CIC play with other senior government officials. The next exercise at this level is expected in 2019.

Status of the finding in the initial mission

Suggestion 22 (S22) is closed as a result of participation of ASN and senior government officials' participation in Major Nuclear Exercises every three years.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

2014 MISSION RECOMMENDATIONS, SUGGESTIONS	
S23	Suggestion: The Government should consider undertaking a review of the regulatory framework for the control of medical exposure to ensure there are no gaps and that the organizations involved are properly coordinated.
R13	Recommendation: ASN should take the necessary steps to ensure that the radiological QA requirements, as set out in the PHC, are implemented for all medical practises. These requirements should assure that there are no gaps in the QC of equipment used for medical exposure and that calibrations of patient dosimetry and sources are traceable to a standard dosimetry laboratory.
R14	Recommendation: ASN should establish DRLs for interventional radiology, and assure for local review of practice if patient doses fall substantially below national DRLs.

Changes since the initial IRRS mission

Suggestion 23: Based on the conclusions of a first action plan on medical imaging (covering the period 2012 to 2017), ASN has developed a second national Radiation Protection action plan which will be published in January 2018. It has been sent (27 September 2017) for approval to the Ministry of Health (MoH) and is focusing on the justification and the optimization of medical imaging practices. The coordination of this action plan will be done by ASN. In regards to radiotherapy, there is no such plan but the coordination will continue to be done by INCA (Institut National du Cancer).

Regarding the setting of referral guidelines, a new decree modifying the Public Health Code (PHC) will establish the MoH as the organisation in charge of the validation of guidelines, which are prepared by the medical scientific societies.

New practices involving the use of ionising radiation can be validated on a “case by case” basis by the MoH by a specific order (R.1333-36.2 and R.1333-36.3). For these practices, the collection of patient data and the assessment of the justification as requested by the MoH will have to be done.

In order to ensure coherence, ASN is setting up a survey committee with all stakeholders whose role will be to examine new innovative practices and new techniques, which were not previously validated.

Recommendation 13: Ordinance n°2016-128 issued on 10 February 2016 clarified and strengthened the regulatory framework of QA for medical practices. QA was mandatory for all medical practices since 2003 but effectively only in place in radiotherapy. The new provision requires:

“Article L. 1333-19.-I.-Procedures using ionizing radiation performed for medical diagnosis, therapeutic treatment, screening, prevention or biomedical research purposes are subject to a quality assurance obligation from the justification of the choice of procedure and optimization of the doses delivered to the patients through, to the procedure results report.”

For the implementation of this provision, ASN has published a decision on quality management systems in radiotherapy (2008) and is preparing a new decision on medical imaging (to be published in 2018). Quality control (QC) of equipment is a part of QA. This new decision is part of the National Cancer Plan (2014-2019).

For each medical device emitting ionizing radiation, internal QC has to be achieved by the Medical Physicist and an external QC has also to be completed by specific bodies appointed by the DG of the French National Agency for Medicines and Health Products Safety (ANSM), in charge of the control of medical devices. The frequency and the modalities of QC are defined by ANSM. ASN inspectors check the practical implementation of this regulation (QC and maintenance) and, if necessary, communicate to ANSM if the QC has not been performed. A protocol between ANSM and ASN defines the means of collaboration between both authorities.

The ASN responsibilities in this field have been strengthened by Ordinance n°2016-128. In addition, a specific requirement underlined the ASN legal competence to control the practical use of medical devices emitting ionizing radiation (HPC, Article L. 1333-30).

A decree is in preparation that will allow bodies appointed by ASN (for the technical control of radiation protection) to check the practical implementation of provisions related to QC and maintenance (R.1333-134), particularly for medical practices that are rarely inspected by ASN (i.e. conventional and dental radiology).

Calibration of patient dosimetry is covered by the ministerial order of 20 November 2007. This is performed by accredited bodies following NF EN ISO/CEI 17020 and NF EN ISO/CEI 17025. The calibration of sources is covered by the ASN resolution 2010-DC-0175 and is performed by bodies appointed by ASN following NF EN ISO 17025. The reference laboratory is the LNE (Laboratoire National d'Essai).

Recommendation 14: France is currently working on the transposition of the European directive 2013/59/Euratom into the national legislation. Legislative terms have been defined in the Ordinance n°2016-128. A decree in preparation aims at modifying the Public Health Code (R. 1333-40.I and II) to add a requirement to evaluate the doses delivered to patients during interventional radiology practices on a regular basis and to transmit the corresponding results to IRSN.

Therefore, in future, interventional radiology practices will be included in the existing process to define and update DRLs. For practices deemed to be of importance in terms of radioprotection, ASN will issue DRLs on a regular basis, taking into account the analyses performed by IRSN on the data received.

Status of the finding in the initial mission

Suggestion 23 (S23) is closed on the basis of progress made and confidence in the effective completion of the review of the regulatory framework, and in particular, concerning the role and the responsibilities of the MoH.

Recommendation 13 (R13) is closed on the basis of progress made and confidence in the effective completion as the legislation has been completed in order to ensure that the radiological QA requirements will be fully implemented for all medical practices.

Recommendation 14 (R14) is closed on the basis of progress made and confidence in the effective completion as provisions have been made in such a way that interventional radiology practices will be included in the existing process to define and update DRLs.

11.2. OCCUPATIONAL RADIATION PROTECTION

2014 MISSION RECOMMENDATIONS, SUGGESTIONS	
S24	Suggestion: ASN and the General Direction of Labour should clarify their requirements regarding the radiation protection programme during the authorization process, especially for the installations concerned by the higher risks, including BNIs.
S25	Suggestion: ASN should consider the need for providing guidance on a graded approach of the implementation of the optimization principle. Information collected through inspections should be used in order to ensure coherence in the approaches already developed or still to be developed in installations where ionizing radiations are produced or used.
R15	Recommendation: The Ministry of Labour in close co-operation with ASN should assess and agree on how to provide ASN inspectors and when appropriate the CPR, with a timely and complete access to workers doses recorded in the national dose register (SISERI).
S26	Suggestion: ASN should take advantage of the launch of the national inspection program for radon in the workplace to improve compliance.

Changes since the initial IRRS mission

Suggestion 24: Ordinance n°2016-128 issued 10 February 2016 introduced the clarifications requested by ASN on the authorization process for higher risk installations. It made explicit, for BNIs, that the collective radiation protection measures for the radiation protection of workers are under the responsibility of the operator. Thus, the operator's compliance with radiation protection principles (justification, optimization and limitation – cf. article L. 593-42 of the CoE) is required from the design phase through to the decommissioning phase. The operator's responsibilities are without prejudice to any responsibilities of the employer.

In particular, this clarification makes explicit the requirement on the radiation protection program as regards the authorization process of BNIs, since this authorization process is set as part of the BNIs legislative and regulatory framework. The new legal system recognizes the possibility for ASN, if needed, to develop additional generic requirements for each category of practice or individual requirement in the frame of the authorization process.

These changes also concern all practices submitted to authorization in the Public Health Code as prescribed in Art. L. 1333-7 and Art. L. 1333-8.-I. To clarify the responsibilities of the operators and of the employers, the Public Health code provides that:

“Art. L. 1333-27.- The prescriptions, means and measures aiming at protecting the health of workers from ionizing radiation, implemented pursuant to the present chapter and chapter VII of this title concern the collective protection measures to be taken by the party responsible for a nuclear activity and designed to ensure compliance with the radiation protection principles defined in Article L. 1333-2.

These measures concern the design, operation and decommissioning phases of the installation and are without prejudice to the obligations incumbent on the employer in application of articles L. 4121-1 et seq. of the Labour Code.”

Suggestion 25: A specific workshop was organized by ASN in December 2016 on the issue of the practical implementation of the ALARA principle, involving stakeholders and ASN inspectors. The experience from BNIs was presented and the opportunity and feasibility to extend this approach, particularly to interventional radiology, were discussed. The need for specific guidance in interventional radiology was underlined, but the reinforcement of the regulatory framework was also suggested. ASN gathered information and considered the need for providing guidance on a graded approach of the implementation of the optimization principle.

In 2017, ASN requested to its advisory Committee for Medical Exposure (GPMED) to prepare recommendations on this topic and the issue of guidance will be discussed in 2018 in consultation with the Ministry of Labour.

On 14 March 2017, ASN produced a resolution concerning the permanent training of professionals on radiation protection of people exposed to ionizing radiations for medical purposes. The objective n°4 in art.4 of this resolution deals with the training of radiologists in optimization. Similar objectives are also presented for other medical areas. This resolution will allow for the further development of training guides by the scientific societies. These guides will have to be approved by ASN.

Recommendation 15: The decree in preparation modifying the Labour Code, for the transposition of the European directive 2013/59/EURATOM “BSS”, specifies that radiation protection inspectors are authorized to enforce the requirements expressed within the Labour Code concerning the radiation protection of workers (new article L.1333-30 of the Public Health Code). Therefore, ASN radiation protection inspectors will have access to the necessary elements and data to perform this control, which includes access to workers’ effective doses and external doses, included in the national dose register SISERI (Information System on Exposure to Ionizing Radiations).

According to this decree, the Radiation Protection Advisor (RPA) (covering both Radiological Protection Expert (RPE) and Radiation Protection Officer (RPO) as expressed within the European directive) has direct access to the workers’ effective doses and external doses in the national dose register. Concerning internal doses, the Ordinance n° 2016-128 issued on 10 February 2016 allows the RPA to get any information relevant for occupational radiation protection and covered by medical confidentiality from the occupational physician:

“Art. L. 4451-2. – By way of exception to article 226-13 of the Penal Code, the occupational physician can transmit to the person designated by the employer to advise said employer with regard to occupational radiation protection, all elements or information covered by professional secrecy on condition that their transmission is limited to those strictly necessary for the exercise of the person's duty.”

“Art. L. 4451-3. – The person designated by the employer to advise said employer with regard to occupational radiation protection is bound by professional secrecy subject to the penalties and under the conditions provided for in articles 226-13 and 226-14 of the Penal Code, with respect to the data covered by the obligation of professional secrecy which were communicated to him by the occupational physician in application of article L. 4451-2.”

Considering the constructive evolution since the first IRRS mission in 2006 and the second IRRS mission in 2014 and the changes which have to be made in the legal framework (new Article L. 1333-30 of the PHC), the team considers that, under the coordination of ASN and in close co-operation with IRSN, full compliance with these new legal requirements could be achieved in the coming months.

Suggestion 26: The regulatory framework on radon in workplaces is currently being updated, taking into account the new requirements of the European “BSS” Directive. For the practical implementation of this new regulation, the 3rd national radon action plan (2016-2019) issued in January 2017, already underlines the need for a global communication strategy directed towards different stakeholders, including employers. This will be completed before 2020.

As a result of the mission concluded by ASN in May 2017 about the review of the oversight of small-scale nuclear activities, concerning the control of radon in workplaces in installations other than the BNIs, it appeared that there is a need for targeting such controls in a more efficient way. A new strategy was developed and approved by the ASN Commission but has still to be discussed with the MoH and MoL. The main elements of the strategy for places where the public is present are the provision of information to the local stakeholders, the collection of the available radon data in order to identify the locations where there are gaps, a reminder to the stakeholders to take actions if needed and finally, to plan inspections targeted on places with such gaps. For locations where both the public and workers are present, a collaboration will be initiated between ASN, the regional agencies for health (ARS) (who are already in charge of the actions needed to protect the public from radon exposure), and the regional Labour services (DIREECTE), in order to deal with the protection of the public and workers. For the locations where workers might be occupationally exposed, the ASN inspectors will integrate the radon issue in their inspections. At the end of 2017, an internal document will describe more precisely the roles of the ASN regarding the radon issue. The operational phase of this program will start in 2018-2019. In the meantime, a new mapping of radon prone areas in France has been performed by IRSN using the criteria of the uranium concentration in the soil.

The newly completed inspection program will include inspection of practices located in radon prone areas that are already visited by ASN inspectors due to their use of sources of ionizing radiation.

Status of the finding in the initial mission

Suggestion 24 (S24) is closed as the requirements regarding the radiation protection program during the authorization process for the installations concerned by the higher risks are now set out in legislation.

Suggestion 25 (S25) is closed on basis of progress made and confidence in the effective completion as a process is underway which will lead to the development of guidance material on the optimization principle in medical practices.

Recommendation 15 (R15) is closed on basis of progress made and confidence in the effective completion of the remaining actions to be undertaken by ASN in close co-operation with IRSN to allow ASN inspectors timely access to worker dose information.

Suggestion 26 (S26) is closed on basis of progress made and confidence in the effective completion as ASN has developed, in the framework of the third national action plan on radon, a strategy (graded approach) aimed at improving compliance with the regulatory requirements in radon prone areas.

11.3. CONTROL OF DISCHARGES, MATERIALS FOR CLEARANCE, AND CHRONIC EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

There were no findings in this area in the initial IRRS mission.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

2014 MISSION RECOMMENDATIONS, SUGGESTIONS

- R16**
- Recommendation:** The Government should consider to establish legal basis for:
- Allocating responsibilities on security matters for BNI and ICPE facilities to ASN, so it is to be entitled to carry out both assessment and oversight activities related to safety-security interfaces.
 - Identifying the responsible authority for both authorization and control in relation to security of radioactive sources

Changes since the initial IRRS mission

Recommendation 16: Regarding the first part of the recommendation, the government did not decide to place ASN in charge of the security for BNIs and ICPE facilities. A department within the Ministry of Ecological and Solidary Transition (The Department of Nuclear Security (DSN) reporting to the General Secretary of the High Official for Defence and Security (HFDS)) has the responsibility for ensuring security of nuclear facilities and nuclear transports.

To carry out both assessment and oversight activities related to safety-security interfaces, ASN works with the DSN, which validates the security studies prepared by nuclear operators. ASN and DSN regularly exchange pertinent information and organize periodic meetings where safety-security interfaces are examined. Discussions take place at two levels:

- at the level of General Directorate of ASN and Deputy HFDS approximately every 6 months,
- at the expert level through meetings of working groups in charge of safety-security interfaces (3 or 4 times a year) that also include IRSN participation.

Information sharing between ASN and DSN will be better formalized when an update to an agreement dating back to 2005 is finalized (see S30). In practice, DSN and ASN are essentially operating as intended by this forthcoming convention on the organization of the Nuclear Safety Authority and the Security Authority to exchange on subjects related to security and nuclear safety.

Regarding the second part of the recommendation, Ordinance n° 2016-128 of the 10th of February 2016 allocates the following responsibilities regarding the security of radioactive sources:

- Ministry of Defence is responsible for the security of radioactive sources that are used in defence facilities,
- Ministry of Ecological and Solidary Transition is responsible for the security of radioactive sources in nuclear facilities that are authorized under the code of defence for the security of nuclear materials,
- ASN is responsible for all the other radioactive sources, mainly in the industrial, research and medical fields.

This Ordinance will soon be supplemented by a decree transposing the European Basic Safety Standards Directive and amending the Public Health Code, Environment Code, Defence Code, Mining and Homeland Security Code and the Labour Code. The ASN gave its opinion on this draft decree on February 23, 2017 (ASN Opinion No 2017-AV-0289). In preparation for assuming this responsibility, ASN has acquired additional staff to conduct the expected inspection and review

activities. In addition, there has been substantial training of many of the involved staff to assure they are well versed in source security techniques and are prepared for implementing the requirements that will be contained in the decree. Notwithstanding these notable efforts, much work remains to establish a viable regulatory and inspection program in this area of new responsibility.

Status of the finding in the initial mission

Recommendation 16 (R16) is closed on the basis of progress made and confidence in the effective completion. The first part of the recommendation is essentially not applicable due to the government’s decision to not allocate security responsibility for BNIs and ICPEs to ASN. With respect to the second part of the recommendation, the progress made to date, in addition to the decree that is soon to be finalized, provide adequate confidence that ASN’s role in security of radioactive sources, mainly in the industrial, research and medical fields, will be appropriately implemented.

12.2. REGULATORY OVERSIGHT ACTIVITY

2014 MISSION RECOMMENDATIONS, SUGGESTIONS	
S27	Suggestion: The Regulatory Body should consider including, in its inspection and assessment programme for BNI and ICPE facilities, activities to verify that security measures in place do not impair safety, especially in case of an accident.
S28	Suggestion: The Regulatory Body should consider incorporating to its training program topics related to safety/security interface of facilities and activities.

Changes since the initial IRRS mission

Suggestion 27: Control of security measures in BNIs is the responsibility of the Department for Nuclear Security (DSN) within the Ministry of Ecological and Solidary Transition.

Regarding review and assessment activities, the DSN communicates to ASN information about safety impacts that may result from malicious acts, including accident situations, and the study of their consequences. This information is to be documented in a separate part of the safety report, as required by an ASN resolution of 12 November 2015 (article 2.4).

Regarding inspections, in May 2016 and February 2017, a team of ASN inspectors (including an inspector specialised in radioactive substance transportation issues) conducted inspections at the headquarters of carriers of radioactive substances and nuclear materials to evaluate their emergency preparedness and response organizations. These inspections were carried out concomitantly with inspections of the Department for Nuclear Security. Both authorities agreed to participate in one common inspection per year, beginning with the field of radioactive substance transportation. However, conducting such inspections at BNIs and ICPEs is yet to take place, though such an approach is being discussed. Article 6 of a draft convention to be co-signed by HFDS and ASN (as discussed in Suggestion 30) discusses the agreement to conduct one concomitant inspection on an annual basis. Additionally, Article 7 of the same draft document discusses expectations that ASN and HFDS participate in exercises organized by the other authority, including national security protection and evaluation exercises (EPEES).

DSN representatives indicated that there is a high reliance placed on operators to identify safety/security interface issues. Notwithstanding, the cooperation between ASN and DSN requires

further strengthening to verify that security measures in place do not impair safety, especially in case of an accident.

Suggestion 28: Since 1 September 2016, ASN has recruited a new Security Officer who has knowledge in the protection of nuclear materials and facilities containing such materials against malicious acts. His mission is to facilitate exchanges between ASN and DSN which deals with these topics.

At the meeting on October 24, 2016, between these two entities, it has been decided:

- to organize training seminars for ASN agents on security issues, with the participation of DSN, and
- to integrate into the training program of each entity a module presenting the activities of the other entity.

These decisions are formalized in the minutes of the meeting. ASN has also integrated in its intranet a webpage about certain general security matters, including methods to protect sensitive information and requirements and procedures for obtaining a security clearance.

In addition, two lectures about general security topics were organized at ASN headquarters to sensitize ASN management and inspectors to these issues. Also, ASN has begun to integrate into its training program topics related to safety/security interface of facilities and activities. In discussions with HFDS and DSN representatives, they noted that they had conducted training of safety/security interface issues at a number of the regional divisions and that they are scheduled to conduct a similar training session in 2018 that will include all of the ASN regional divisions.

Status of the finding in the initial mission

Suggestion 27 (S27) remains open due to the need for continued progress towards coordinated inspections at BNIs and ICPEs between ASN and DSN.

Suggestion 28 (S28) is closed on the basis of progress made and confidence in the effective completion based on efforts to date, as well as what seems to be an improving relationship with HFDS/DSN on a wide variety issues of common interest, including training.

12.3. INTERFACE WITH OTHER AUTHORITIES

2014 MISSION RECOMMENDATIONS, SUGGESTIONS	
S29	Suggestion: The ASN should consider coordinating with Department for Nuclear Security to develop joint inspection programs on safety and security issues on a regular basis.
S30	Suggestion: ASN should consider updating of the convention for co-operation with authorities in charge of security of nuclear facilities.

Changes since the initial IRRS mission

Suggestion 29: Control of security measures in BNIs is the responsibility of the authority in charge of protection against malicious acts HFDS/DSN. As noted earlier, in May 2016 and February 2017, a team of ASN inspectors (including an inspector specialised in radioactive substance transportation issues) conducted inspections at the headquarters of carriers of radioactive substances and nuclear materials, on their emergency preparedness and response organization.

These inspections were carried out concomitantly with inspections of the Department for Nuclear Security. While this area has a good degree of commonality that one could consider them to be a joint inspection, to do so at BNIs and ICPEs is a very unlikely outcome due to the differing focus areas and being able to create a “need to know” basis for participation in security inspections. A more appropriate approach that is being pursued that could improve the understanding of safety/security interfaces is to conduct simultaneous inspections vice conducting “joint” inspections.

With respect to the 2016 and 2017 inspections noted above, in order to improve further partnership during inspections on this topic and develop a better understanding and assessment of the safety/security interface, both authorities cooperated to design a common framework of issues to investigate. However, to ensure the confidentiality of their respective recommendations, the inspectors agreed to report separately to the carrier at the end of the inspection. Both authorities agreed to reiterate at least one coordinated inspection per year, beginning with the field of radioactive substance transportation. This was discussed in Suggestion 27, as were the efforts to better coordinate on emergency exercises.

Suggestion 30: As noted in the discussion of the status of Recommendation 16, the government decided that the Department for Nuclear Security (DSN) of the Ministry for Ecological and Solidary Transition would continue to be responsible for ensuring the security for nuclear facilities.

As noted earlier, ASN has worked more closely with HFDS/DSN over the last several years. This includes the establishment of specific points of contact at DSN and ASN, who are responsible for exchanging appropriate information and organizing periodic meetings where safety/security interfaces are discussed amongst various organizational levels.

An update to a 2005 convention for co-operation between HFDS/DSN and ASN is currently under development and should be finalized by early 2018. This update will greatly improve the documented working relationship between DSN and ASN and better formalize the practices that are currently ongoing or are envisioned for how the two organizations will work together.

Status of the finding in the initial mission

Suggestion 29 (S29) is closed on the basis of progress made and confidence in the effective completion. Developing joint inspections at a BNI/ICPE is not a reasonable expectation given the existing roles and responsibilities that have been established. However, both ASN and DSN have already conducted several coordinated inspection activities in the transportation area, and are actively looking at how to expand upon that concept as well in other areas.

Suggestion 30 (S30) is closed on the basis of progress made and confidence in effective completion. A revised version of the convention on the organization of ASN and DSN to exchange on subjects related to security and nuclear safety has been drafted and commented on by both ASN and DSN and is expected to be finalized in the coming months.

Policy Discussion 3

The regulatory framework for control of the security of radioactive sources

In 2015, the “Energy transition law” authorized the Government to establish provisions against malicious acts upon nuclear activities and in 2016, the “Nuclear ordinance” compelled the persons in charge of a nuclear activity to implement protection against malicious acts and identified the authorities both for authorization and control regarding security of radioactive sources. ASN is, with a few exceptions such as NPPs or facilities run by the Defence Department, the regulatory body for the security of sources. Currently, two draft regulations are under development: a draft

Decree that includes regulatory security provisions and a draft ministerial Order with detailed provisions for the security of radioactive sources. These are expected to be published in 2018 and be enforced in 2019 (with transitional arrangements). Therefore, in addition to contributing to the drafting of the regulations and performing visits at sites to exchange information with operators, ASN has initiated preparation for this new responsibility by creating a new security unit with three engineers within the transport and source department, initiating internal training on security and developing internal guidance for the assessment of future applications and future inspection of facilities.

The IRRS team supported the approach that ASN has initiated. The team noted that they faced a similar situation after the events of 9/11. After those events the security of sealed sources became a more significant issue for many governments. One team member noted that their agency addressed this situation in a phased approach and established a grace period before taking any enforcement actions. This provided licensees an opportunity to better meet the new requirements and for the regulator to ensure that these requirements are appropriate.

The IRRS team recommended applying a graded approach, which is consistent with ASN's priority to focus on the security of high activity sealed sources. The team also noted that ASN should pay attention to those disused sources. The team recommended ASN to continue benchmarking with other countries that have already established and implemented requirements and processes for authorizing and inspecting the security of radioactive sources. In addition, France should focus on the transitional arrangements related to the new security regulations to enable source users to plan, finance and implement the new security measures.

The team recommended that ASN develop a single organizational culture that embeds both security and safety. The team noted that experience had shown that maintaining separate security and safety cultures creates confusion for licensee and regulatory bodies.

The team also suggested that, based on their experience, ASN should combine the authorization and inspection process for safety and security, after providing the inspectors with appropriate training and guidance. Several IRRS team members noted that doing so has been successful in their countries.

ASN noted a concern with the possible lack of transparency of not disclosing the results of security inspections to the public. In that regard, the IRRS team members discussed their experiences in sharing some general information about security but keeping the more detailed or confidential information which could compromise the security of a facility out of the public domain.

Finally, the IRRS team recommended that ASN coordinate early with the all involved interested parties when implementing any new requirements for the security of radioactive sources.

IRRS FOLLOW-UP MISSION TEAM



APPENDIX I - LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
DEAN Bill	U.S. Nuclear Regulatory Commission (NRC, retired)	billdean777@gmail.com
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WILDERMANN Thomas	Ministry of Environment, Climate Protection and the Energy Sector (UMBW)	thomas.wildermann@um.bwl.de
IAEA STAFF MEMBERS		
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APPENDIX II - MISSION PROGRAMME

Time	Sun 1 October	Mon 2 October	Tue 3 October	Wed 4 October	Thu 5 October	Fri 6 October	Sat 7 October	Sun 8 October	Mon 9 October
9:00-10:00	Team Arrival	Entrance Meeting	Interviews	Discussion of findings with counterpart	Cross reading	Submission of the Draft Report to the Host	Social Event	Review of host's comments Discussion with the Host	Exit Meeting
10:00-11:00					TL drafts Executive Summary				
11:00-12:00					Discussion of results of cross- reading				
13:00-14:00	Initial Team Meeting	Interviews	Interviews	Final findings with text delivered	Collective reading of the report	Preparation of the press release Host reads report TL prepares presentation Written comments presented by the Host		Final Draft to the Host	Departures of Team Members
14:00-15:00			Discussion of findings/ report by the team		Finalise draft Report				
15:00-16:00			TM finalize findings/ TM write report		Review of the Executive Summary				
16:00-17:00			Team revises report based on discussions		Submission of Report to IRRS Admin				
17:00-18:00		Daily Team Meeting	Daily Team Meeting	Daily Team Meeting	Daily Team Meeting				
20:00-24:00		TM write findings	Secretariat edits findings TM write report	Secretariat edits report TM Read Draft	Secretariat edits Draft Report				

APPENDIX III - MISSION COUNTERPARTS

	IRRS Experts	Lead Counterpart	Support Staff
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT		
	Bill DEAN Ann MCGARRY	Benoit BETTINELLI (MTES), Matthieu SCHULER (IRSN)	Sylvie RODDE, Fabien FERON
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY		
	Kirsi ALM-LYTZ	Ambroise PASCAL	Daniel DELALANDE
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY		
	Kirsi ALM-LYTZ	Ambroise PASCAL	Matthieu SCHULER, Patrice DESCHAMPS (IRSN), Pierre BOQUEL
5.	AUTHORIZATION		
	Jim SCOTT	Julien HUSSE Pierrick JAUNET, Sylvie RODDE	Dominique BOINA Jean-Luc GODET, Fabien FERON, Matthieu SCHULER, Patrice DESCHAMPS (IRSN)
6.	REVIEW AND ASSESSMENT		
	Thomas WILDERMANN	Julien HUSSE Pierrick JAUNET, Sylvie RODDE	Dominique BOINA, Romain PIERRE, Olivier ELSESSOHN, Jean-Luc GODET, Fabien FERON

	IRRS Experts	Lead Counterpart	Support Staff
7.	INSPECTION		
	Jim SCOTT Thomas WILDERMANN	Julien HUSSE Pierrick JAUNET, Sylvie RODDE	Dominique BOINA Ambroise PASCAL, Remy CATTEAU, Stéphanie PEIRO Ghislain FERRAN, Jean-Luc GODET, Fabien FERON
8.	ENFORCEMENT		
	Thomas WILDERMANN	Julien HUSSE Pierrick JAUNET, Sylvie RODDE	Dominique BOINA
9.	REGULATIONS AND GUIDES		
	Kirsi ALM-LYTZ Jim SCOTT	Anne-Cecile RIGAIL Pierrick JAUNET, Sylvie RODDE	Olivia LAHAYE Jean-Luc GODET
10.	EMERGENCY PREPAREDNESS AND RESPONSE		
	Luc SIGOUIN	Jeanne LOYEN, Jean-Francois DODEMAN	Bénédicte GENTHON, Ambroise PASCAL
11.	ADDITIONAL AREAS		
	Pascal DEBOODT	Jean-Luc GODET	Pierrick JAUNET, Matthieu SCHULER, Patrice DESCHAMPS (IRSN)
12.	INTERFACE WITH NUCLEAR SECURITY		
	Bill DEAN Ann MCGARRY	Benedicte GENTHON, Philippe AUBERT	Jeanne LOYEN, Sylvie RODDE, Christophe QUINTIN, Géraldine DANDRIEUX (HFDS)

APPENDIX IV - RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE PREVIOUS IRRS MISSION THAT REMAIN OPEN

Section	Module	R/S	Recommendation/Suggestion
3.1	4	R4	The Government and ASN should explore new ways to ensure that the human and financial resources needed for effective regulation of nuclear and radiation safety are sustained into the future as ASN's workload increases.
4.1	4	S6	ASN should consider updating relevant parts of the management system and associated processes to ensure the management system promotes and supports a strong safety culture in the regulatory body.
6.2	6	S8	The regulatory body should consider issuing internal guidance on the review and assessment activities to be undertaken in the frame of the periodic safety reviews covering all safety factors of SSG-25.
9.1	9	R11	ASN should develop more detailed guidance for the review and renewal of regulations and guides. The guidance should also include regular assessment of the need to renew regulations including updated IAEA safety standards as an initiator for such renewal.
9.5	9	S18	ASN should consider gaining specific expertise and developing specific safety guides (standard format and content of a safety case, site criteria, etc.) related to a near-/sub-surface disposal facility in a timely manner (depending on the options to be proposed by Andra in 2015).
12.2	12	S27	The Regulatory Body should consider including, in its inspection and assessment programme for BNI and ICPE facilities, activities to verify that security measures in place do not impair safety, especially in case of an accident.

APPENDIX V - RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2017 IRRS FOLLOW UP MISSION

Section	Module	RF/SF/GPF	Recommendation, Suggestion or Good Practice
10.2	10	SF1	The regulatory body should consider developing definitions of emergency classes consistent with those defined in GSR Part 7 and ensure operators classify emergency situations and communicate the emergency class to offsite response authorities.

APPENDIX VI - REFERENCE MATERIAL PROVIDED BY ASN

ARM or during the mission	Documents/Reference	Subject
ARM: IRRS-R11	Guide n°25 dated 27/10/16	Preparation of ASN Statutory Resolutions and ASN Guides Conditions for Participation of Stakeholders and the General Public
ARM: IRRS-R12	Letter from the Minister of Interior (NOR: INTER1627472J)	Letter from the Minister of Interior on response to a major nuclear or radiological accident. Change in the national doctrine for the preparation or modification of off-site emergency plans (PPIS) around the nuclear power plants (NPPs) operated by EDF
ARM: IRRS-R2	DGPR/SRT/MSNR/2017-082 dated 27 June 2017	Letter from DGPR to ASN addressing a recommendation resulting from the IRRS mission of 2014
ARM: IRRS-R4	ASN opinion 2017-AV-0294 of 1st June 2017	ASN opinion 2017-AV-0294 of 1st June 2017 concerning the budget for the regulation of nuclear safety and radiation protection in France, for the years 2018 to 2020
ARM: IRRS-R6	Report on the audit of the ASN-IRSN agreement dated December 2016	Report on the audit of the agreement and its appendices binding ASN (Nuclear Safety Authority) and IRSN (Institute for Radiation Protection and Nuclear Safety) conducted on 27 and 28 June 2016
ARM: IRRS-R8	ASN resolution 2015-DC-0521 of 8th September 2015	ASN resolution 2015-DC-0521 of 8th September 2015 relative to the tracking and registration of radionuclides in the form of radioactive sources and products or devices containing them
ARM: IRRS-R9	Procedure SMQ/DEU/QPR/SAN /ASN/000120/2015 (ASN/SAN/120)	Procedure SMQ/DEU/QPR/SAN /ASN/000120/2015 (ASN/SAN/120) - THE PRINCIPLES APPLIED BY ASN WHEN DETERMINING ENFORCEMENT (OR POLICING) MEASURES AND SANCTIONS

ARM: IRRS-S12	BNI No. 167 – Flamanville 3 EPR reactor Report to the ASN Commission	Doctrine for Oversight of the Start-up Tests of the Flamanville 3 EPR Reactor
ARM: IRRS-S19	ASN resolution 2015-DC-0503 of 12th March 2015	ASN resolution 2015-DC-0503 of 12th March 2015 relative to the notification system for companies transporting radioactive substances on French territory
ARM: IRRS-S18	Procedure SMQ/DRC/QPR/AUT/ASN/002410/2015 (ASN/AUT/2410)	Procedure SMQ/DRC/QPR/AUT/ASN/002410/2015 (ASN/AUT/2410) - PERIODIC SAFETY REVIEW OF A LUDD BASIC NUCLEAR INSTALLATION
During the mission	Project of update of the procedure SMQ/SG/QPR/REG/ASN/000100/201x (ASN/REG/100)	Project of update of the REG/100 internal procedure on regulations and guides
During the mission		List of envisaged amendments to the BNI order
During the mission		Table of implementing texts for the decrees of the Labor Code and the Public Health Code transposing Council Directive 2013/59 / EURATOM of 5 December 2013 “BSS”
During the mission		Table of analysis on the transposition in the French regulation of the IAEA safety requirement SSR-2/2
During the mission		Translation of Article 2.4 of the project of ASN Resolution on Safety Report
During the mission		Draft ASN / HFDS convention and translation of some articles

APPENDIX VII - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. **IAEA SAFETY STANDARDS SERIES No. SF-1** - Fundamental Safety Principles
2. **IAEA SAFETY STANDARDS SERIES No. GSR PART 1** - Governmental, Legal and Regulatory Framework for Safety
3. **IAEA SAFETY STANDARDS SERIES No. GSR PART 3** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
4. **IAEA SAFETY STANDARDS SERIES No. GS-R-2** - Preparedness and Response for a Nuclear or Radiological Emergency
5. **IAEA SAFETY STANDARDS SERIES No. GS-R-3** - The Management System for Facilities and Activities
6. **IAEA SAFETY STANDARDS SERIES No. NS-R-1** – Safety of Nuclear Power Plants: Design
7. **IAEA SAFETY STANDARDS SERIES No. NS-R-2** – Safety of Nuclear Power Plants: Operation
8. **IAEA SAFETY STANDARDS SERIES No. NS-R-4** - Safety of Research Reactors
9. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.1**- Organization and Staffing of the Regulatory Body for Nuclear Facilities
10. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.2** - Review and Assessment of Nuclear Facilities by the Regulatory Body
11. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.3**- Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
12. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.4** - Documentation for Use in Regulatory Nuclear Facilities
13. **IAEA SAFETY STANDARDS SERIES No. GS-G-2.1** - Arrangements for Preparedness for a Nuclear or Radiological Emergency
14. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.1** - Application of the Management System for Facilities and Activities
15. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.2** - The Management System for Technical Services in Radiation Safety
16. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.3** - Assessment of Occupational Exposure Due to External Sources of Radiation
17. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.4** - Building Competence in Radiation Protection and the Safe Use of Radiation Sources
18. **IAEA SAFETY STANDARDS SERIES No. NS-G-2.10** - Periodic Safety Review of Nuclear Power Plants Safety Guide
19. **IAEA SAFETY STANDARDS SERIES No. NS-G-211** - A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide
20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).
21. **IAEA SAFETY STANDARDS SERIES No. GSR Part 7** - Preparedness and Response for a Nuclear or Radiological Emergency

APPENDIX VIII - ASN ORGANIZATIONAL CHART

