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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

THE REPUBLIC OF FRANCE

Montrouge, Republic of France

17 to 28 November 2014

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated
Regulatory
Review Service
IAEA IRRS

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Mission date:	*17 to 28 November 2014*
Regulatory body:	*AUTORITE DE SURETE NUCLEAIRE (ASN)*
Location:	*ASN HQ in Montrouge, REPUBLIC OF FRANCE*
Regulated facilities and activities:	*Nuclear power plant, fuel cycle facilities, research reactor, waste management facility, former uranium mine, uses of radiation sources in research and industry and transport, medical exposures, 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 the Republic of France, an international team of senior nuclear safety and radiation protection experts met with representatives of the Autorité de Sûreté Nucléaire (ASN) of the Republic of France from 17 to 28 November 2014 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at ASN Headquarters in Montrouge. The purpose of the IRRS mission was to perform a peer review of France's national regulatory framework for nuclear and radiation safety. As recommended by the IAEA Nuclear Safety Action Plan, special attention was given to regulatory implications of the TEPCO-Fukushima Daiichi accident.

The IRRS mission covered all civilian nuclear and radiological facilities and activities (with the exception of security) regulated by the Republic of France. The review compared the French regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS review team members and the French counterparts in the areas covered by the IRRS.

The IRRS team consisted of 22 senior regulatory experts from 17 IAEA Member States, five IAEA staff members, one IAEA administrative assistant and one observer. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; control of medical exposures, occupational radiation protection, control of radioactive discharges and materials for clearance, environmental monitoring, transport, waste management, decommissioning and interfaces of nuclear safety and security.

The IRRS mission included two policy issue discussions: resources allocated to the regulatory body its primary technical support organization, and its corresponding funding schemes; and safety/security interfaces.

The mission included observations of regulatory activities and interviews and discussions with ASN staff, representatives from the French Parliament, Services of the Prime Minister (SGDSN), Le Haut Comité pour la transparence et l'information sur la sécurité nucléaire (HCTISN) and the Mission for Nuclear Safety and Radiation Protection (MSNR), the Services of the Ministry in Charge of Nuclear Security (MEDDE/HFDS), l'Institut de radioprotection et de sûreté nucléaire (IRSN), and other organizations to help assess the effectiveness of the regulatory system. These activities included visits to: Nogent Nuclear Power Plant; Areva's La Hague site; Institut Laue-Langevin research reactor; CEA Saclay; Centre de Stockage de l'Aube (CSA) and at other industrial and medical facilities. The IRRS team members observed regulated activities and performance of inspection activities by ASN personnel, including discussions with the licensee personnel and management. In addition, the IRRS team observed a national emergency exercise.

In preparation for the IRRS mission the Republic of France conducted a self-assessment and prepared a preliminary action plan to address weaknesses that were identified. The results of the self-assessment and supporting documentation were provided to the team as advance reference material for the mission. Throughout the mission, the IRRS review team was extended full cooperation in the regulatory, technical, and policy issues by all parties in a very open and transparent manner.

The possible implications of the TEPCO Fukushima Daiichi accident on nuclear and radiation facilities in the Republic of France were well recognized by the French regulator(s) in the past,

and the IRRS team did not find any unresolved related issue. The IRRS team considered the concept of hardened safety core as an option for the international nuclear community for further development of the general nuclear design safety concept**.** It was also noted that ASN has emphasized the importance of international cooperation and of further effective steps to make the regulatory body capable of delivering its emergency response reponsibilities in a long lasting nuclear emergency within or in the vicinity of France.

The IRRS team made the following general observations:

- The French regulatory system allows ASN to operate in practice as an independent regulatory body
- ASN has a mature and effective regulatory structure and benefits from the independent advice of IRSN and the Advisory Committees.
- ASN is committed to communication and consultation with interested parties, and transparency in its regulatory activities.

The Republic of France has engaged in an ambitious energy transition policy. The IRRS team acknowledges that the main upcoming challenges in the field of nuclear safety and radiation protection are to continue to reinforce the safety of the existing nuclear facilities, monitoring ageing, commissioning of a new EPR reactor, while addressing the programmatic changes to implement this new policy. Sustained government support for the regulatory body will be needed to ensure the necessary human resources are available for ASN to discharge its regulatory mandate.

The IRRS review team identified a number of good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with IAEA safety standards.

The good practices identified by the IRRS review team include:

- The involvement of stakeholders in the regulatory processes in transparent decision-making in France related to nuclear safety and radiation protection is exemplary. In addition, ASN makes extensive use of communication methods, including its web site to provide information and promote participation in its activities and decisions.
- ASN Commissioners and staff are independent in the performance of their regulatory responsibilities. Throughout the team's interactions with ASN, supporting organizations, and licensees, it was clear that there is a strong commitment to safety.
- The regulatory framework for emergency planning and response exhibits several good practices, such as clear designation of responsibilities, strong coordination between regulatory organizations and a high degree of interaction with licensees.

The IRRS review team identified certain issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system:

- The government should review the regulatory framework to ensure effective coordination between organizations and their regulatory functions, especially for the control of medical exposure and security of radioactive material.
- ASN should enhance its system for reviewing and revising its regulatory framework and should complete its on-going project for developing technical resolutions and guidelines. A graded approach should be clearly adopted across all ASN regulatory functions.
- ASN management system should be completed and fully implemented, in an integrated manner for all processes needed to deliver ASN's mandate in particular safety culture should be addressed.

- The question over the adequacy of the human and financial resource needed for ASN to discharge its regulatory responsibilities in an effective manner.

The IRRS team noted that many of the issues were identified in the Action Plan provided in the advanced review material. Therefore, the Republic of France has already begun to address several of the recommendations and suggestions identified by the IRRS team.

The IRRS review team findings are summarized in Appendix IV.

An IAEA press release was issued at the end of the IRRS Mission.

I. INTRODUCTION

At the request of the Government of the Republic of France, an international team of senior safety experts met representatives of Autorite de Surete Nucleire (ASN) of the Republic of France from 17 to 28 November 2014 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the peer review was to review the French regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of France in January 2012. A preparatory mission was conducted from the 27 to 28 of May 2014 at ASN Headquarters in Montrouge, France to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the facilities regulated by ASN and selected safety aspects.

The IRRS team consisted of 22 senior regulatory experts from 17 IAEA Member States, five IAEA staff members, one IAEA administrative assistant and one observer. The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, public and environmental exposure control, transport, waste management and decommissioning. As recommended by the IAEA Nuclear Safety Action Plan, special attention was given to regulatory implications in the French framework for safety of the TEPCO-Fukushima Dai-ichi accident.

In addition, two policy issues were discussed in connection to the resources allocated to the regulatory body the technical support organization, and its corresponding funding schemes; and safety/security interfaces.

ASN conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of ASNs' self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from ASN and performed direct observation of ASNs' working practices during inspections. Meetings with the Services of the Prime Minister (SGDSN) and the Ministry the Ministry in Charge of Nuclear Security (MEDDE/HFDS) were also organized.

All through the mission the IRRS team received excellent support and cooperation from ASN.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Frances' radiation and nuclear safety regulatory framework and activities to review its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities regulated by ASN with the exception of security. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

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

The key objectives of this mission were to enhance nuclear and radiation safety, emergency preparedness and response:

- Providing the Republic of France and ASN, through completion of the IRRS questionnaire, with an opportunity for self-assessment of its activities against IAEA safety standards;
- Providing the Republic of France and ASN, with a review of its regulatory programme and policy issues relating to nuclear and radiation safety, and emergency preparedness;
- Providing the Republic of France and ASN, with an objective evaluation of its nuclear safety, and emergency preparedness and response regulatory activities with respect to IAEA safety standards;
- Contributing to the harmonization of regulatory approaches among IAEA Member States;
- Promoting the sharing of experience and exchange of lessons learned;
- Providing reviewers from IAEA Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own fields;
- Providing key ASN staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- Providing the Republic of France and ASN, with recommendations and suggestions for improvement; and
- Providing other States with information regarding good practices identified in the course of the review.

III. BASIS FOR REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of the Republic of France, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 27 to 28 of May 2014. The preparatory meeting was carried out by the appointed Team Leader Mr Mark Satorius, Deputy Team Leader Ms Ann McGarry and the IRRS IAEA Team representatives, Ms Adriana Nicic, Mr Belkacem Djermouni and Mr Jean-Francois LaFortune.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of ASN represented by Mr Pierre-Franck Chevet, President of ASN, Mr Philippe Jamet, Commissioner, Mr Jean-Christophe Niel, Director Genral, other senior management and staff. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS mission:

- Nuclear power plants;
- Fuel cycle facilities;
- Waste facilities;
- Radiation sources facilities;
- Decommissioning;
- Transport;
- Patient protection;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Waste management (policy and strategy, predisposal and disposal);
- Regulatory implications of the TEPCO Fukushima Dai-ichi accident; and
- Selected policy issues.

Mr Niel, Mr Osouf and other ASN staff made presentations on the national context, and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in France in November 2014.

The proposed IRRS Review team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS Review team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The French Liaison Officer for the preparatory meeting and the IRRS mission was Nicolas Osouf.

ASN provided the IAEA (and the review team) with the advance reference material for the review at the end of September 2014, including the self-assessment results. In preparation for the mission, the IAEA review team members 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 IRRS 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 the reference for this mission is given in Appendix VI.

C) CONDUCT OF THE REVIEW

An opening IRRS Review team meeting was conducted on Sunday, 16 November 201 in Paris, France by the IRRS Team Leader and the IRRS 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.

In addition, the IAEA Team Coordinator and Review Area Facilitator presented the expectations regarding the module on the "Regulatory implications from TEPCO-Fukushima Dai-ichi Accident" to be applied.

The Liaison Officer was present at the opening IRRS Review team meeting, in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

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

The IRRS entrance meeting was held on Monday, 17 November, 2014, with the participation of ASN senior management and staff as well as of IRSN staff. Opening remarks were made by Mr Pierre-Franck Chevet, President of ASN, Mr Mark Satorius, IRRS Team Leader and Ms Ann McGarry, IRRS Team Coordinator. Mr Jean-Christophe Niel gave an overview of the French context, and Mr Nicolas Osouf presented the action plan prepared as a result of the self-assessment.

During the mission, a review was conducted for all the review areas with the objective of providing the Republic of France and ASN with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national practices and activities.

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

The IRRS exit meeting was held on Friday, 28 November, 2014. The opening remarks at the exit meeting were presented by Mr Jean-Christophe Niel and Mr Pierre-Franck Chevet and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Mark Satorius. Closing remarks were made by Mr James E. Lyons, IAEA Director, Division of Nuclear Installation Safety.

A joint IAEA and ASN press conference took place at the end of the mission during which an IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

France has developed the necessary legislative and regulatory framework for the protection of people and the environment against the harmful effects of the use of nuclear energy and ionizing radiation. France has signed and ratified all international conventions related nuclear safety and radiation protection. In some cases the commitments in the international conventions have been transposed into the national law.

Legal background which grants the ASN the authority to perform regulatory inspections and enforcement actions is given by the Environmental Code, Labour Code and the Public Health Code, and appears to be, with some exceptions, sufficient. These exceptions are addressed in the Report. Based on these Codes, ASN inspectors can perform all activities needed to carry out regulatory inspections assumed to be performed in the IAEA standards with the exception of inspections outside the BNIs. Though ASN can take appropriate enforcement actions, currently more precise gradation of sanctions is being developed.

The IRRS team has established that France has no specific single document that contains the national strategy and policy for safety. However the relevant acts, namely the Environmental Code, the Public Health Code and the Labour Code, taken together with the regulations made under these codes, contain most of the fundamental safety principles and set out the safety objectives established in the IAEA safety fundamentals.

The IRRS team noted that France follows a graded approach. The graded approach is laid down for the BNIs in the Environmental Code. For other activities, it is covered only in a general way. ASN as the regulator gives the authorization and provides for inspection. Its inspection plan uses a graded approach based on the risk associated with the facility. The regulations planned to transpose the new EU BSS will contain the graded approach for radiation sources.

France applies the IAEA Code of Conduct of Radiation Sources.

There is no commitment from the government to assure resources provision to ASN (see Module 3).

ASN and IRSN jointly developed a proposal “Reinforcing the nuclear safety oversight structure in the context of the energy transition” where the above challenges were explained. It also includes the proposal to consider funds contributions directly from major nuclear licensees. The government asked ASN to make a public judgement of their proposal. Currently the regulations establishing ASN do not include any commitment from the government to assure resources provision to the regulatory body. There is a general statement in law to provide the appropriate resources by the nuclear operators. There is no requirement for other licensees to devote enough resources for nuclear safety and radiation protection of the facilities.

There are no direct provisions related to safety culture included in the national regulations, only some of its aspects appear, but not systematically. There is an ASN Decision under consultation which will explicitly address safety culture of BNIs.

ASN decisions are published on the ASN Website for public comment before they are issued. A national high committee (High Committee for Transparency and Information on Nuclear Safety, HCTISN) and Local Information Committees (LCI) around BNI facilities partly funded by the government, , local governments and ASN provide direct, organized and transparent opportunity for the public to gain information and influence decisions. However the government funding of these committees are not laid down in law. ASN responds to all questions submitted by the public via electronic means.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Most of the elements of the national policy and strategy for safety are covered in French legislation, however some are missing. Specifically safety fundamentals and objectives are not systematically and uniformly included in the French legislation.*	
(1)	**BASIS: GSR Part 1 para. 2.3 (a) states that** *"National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:* *(a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles;"*
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.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *France has established a national high committee (High Committee for Transparency and Information on Nuclear Safety, HCTISN) in law to act as an independent consultative body on nuclear related issues. Local Information Committees are also established around each nuclear power plant to provide forums for debate at the local level. The Environmental Code set out public rights to information on radiation and nuclear safety. Any person is entitled to obtain from the BNI licensee or persons responsible for the transportation or holding of radioactive sources, information on the risks related to ionising radiation and on the safety and radiation protection measures to prevent or reduce the risks or exposures. As the regulatory body, ASN submits key resolutions to public consultation and publishes the most important decisions on is website.*	
(1)	**BASIS: GSR Part 1 Para. 2.5.(5) states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *(5) Provision for the involvement of interested parties and for their input to decision making;"*
(2)	**BASIS: GSR Part 1 Para. 4.27 states that** *"The regulatory body shall also inform and consult interested parties in relation to the basis for such proposed changes in regulatory requirements."*
(3)	**BASIS: GSR Part 1 Para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience."
GP1	**Good Practice: The IRRS Team considers that the efforts at the government level in France to establish a framework for the provision of information and the engagement of stakeholders in transparent decision making related to nuclear safety and radiation protection is exemplary. Committees such as the HCTISN and the CLIs to foster participation of interested parties are required by law.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Environmental Code and the Public Health Code provide a comprehensive framework for nuclear and radiation safety in France. The laws differentiate between the various applications of nuclear energy and ionizing radiation and require the authorization for each type. The Environmental Code created ASN and tasked with the regulation and supervision of nuclear and radiation safety. The ASN is a regulatory body in that it is empowered to issue obligatory technical decision approved by the relevant minister and non-mandatory guidelines. The decision of ASN can be appealed before the judiciary and can be inquired by a third party.

The authorization processes related to nuclear safety and radiation protection are conducted by ASN and ministry of ecology (described in Module 5 in details). In the medical field, ASN is not in charge of authorizing medical devices (ANSM is in charge), whereas the control of radon exposure is shared between ASN and the Health authorities. ASN gives advice on RP issues when asked to do so.

The French law make it mandatory to involve the public into all the decisions that affect the environment and provide for the continued responsibility should any change in the owner or operator of a facility or activity take place.

The types of facilities and activities that are included within the scope of the framework for safety are contained in the Environment Code and the Public Health Code.

The laws detail the extent to which the national framework for safety specifies responsibilities and obligations including financial provisions for the management of radioactive waste and spent fuel, for decommissioning of facilities, and termination of activities.

The ASN staffs consist of Civil Servants (335) and employees from IRSN and CEA (104) and specially contracted work force (49). ASN is not an independent employer, since the civil servants are obliged to change organization regularly, approximately every four to five years (in 2013 about 60 persons were replaced). Therefore a very robust training programme is going on at all times in ASN. Every newcomer needs a full year of training. The IRSN supports the continuity in management of knowledge. ASN is an attractive workplace among Civil Servants. According to ASN experiences the system is basically good, but the duration that the civil servants spend in ASN is too short and should be extended to six to seven years.

A safety report is prepared in which the safety performance of facilities is evaluated. This is described to the parliament and press conferences are organized.

The exemption from regulatory control of activities is determined for all the different types of activities. For radioactive waste it is not permitted. The inventory of radiation sources is

managed by IRSN Regulatory supervision of import-export of radioactive substances is covered by the law in accordance with the guidance of the Code of Conduct.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

According to Environmental Code, the nuclear safety authority is the ASN, which is an independent administrative authority responsible for supervising civilian nuclear activities in France. The ASN ensures, on behalf of the State, the control of nuclear safety and radiation protection in France to protect workers, patients, the public and the environment from risks related to nuclear activities. The ASN takes part in the regulation of safety and takes technical decisions, authorizes the operators of facilities and activities and inspects the compliance of them with the law; furthermore it informs the public about its activities. ASN is authorized to take enforcement steps. The Project Law under consultation will provide wider and simpler opportunities for ASN to define sanctions if regulations are violated.

The ASN is independent from the operators and licensee of facilities and activities and is free of conflicting responsibilities. Strict rules relate to ASN staff members, as to civil servants regarding being independent of the regulated organizations.

Observations related to the resources of ASN are discussed under Section 1.1.

ASN is authorized to carry out regulatory inspections only within the perimeter of the operators. In practice they inspect EDF at the contractors, manufacturers and technical supports as well, but not the contractors and technical supports themselves. ASN proposed a law to change the situation and be able to perform the inspections at and of the subcontractors. This issue has been identified by the IRRS team also in Module 7 regarding inspections.

In the French legislation competences and responsibilities in nuclear and radiation safety are provided to authorities above the ASN. Namely there is a minister in charge of nuclear safety and a Mission for Nuclear Safety and Radiation Protection (MSNR). Currently the minister of ecology assumes this responsibility, which is also responsible for energy. Within the organization of the ministry the Directorate General for Risk Prevention (DGPR) contains the MSNR. The ASN meets at various levels with both the DGPR and the MSNR: twice a year with the DGPR along jointly developed agendas and several times with MSNR. The role of the DGPR in the field of nuclear and radiation safety is to take part in law-making, emergency preparedness, public communication, foreign relations and research and development. All the laws proposed by ASN are coordinated between the MSNR and ASN. The MSNR has 8 staff members. 2 of them have worked in ASN before. The cooperation is governed by a MoU.

The constitution gives the exclusive right to the government to make effective regulations. ASN can take effective decisions that have legal force. If a decision is taken for multiple plants, it is regarded as a regulation and is subject to a so-called homologation process in which the government can veto the decision. The decision however cannot be modified by the government. The whole process takes place publicly.

ASN can also turn to a member of the Parliament to make a proposal to modify or create a law.

Parliament reviews ASN activities through annual reports and hearings. Questions can be taken to ASN by the members of the Parliament.

ASN has to comply with time constraints regarding the various authorization processes. If the relevant one is not met in the procedure, the decision can be queried. If no decision is taken it is not possible to carry out the applied activity. The time constraints are not narrow and in most cases are met so they do not impair the grounding of the decisions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The ASN is allowed by legislation to carry out regulatory inspections only in authorised premises of BNI and ICPE facilities. There are also some gaps in ASNs authority to inspect in the medical area. That impairs its inspection effectiveness as it is not able to carry out oversight activities for example those done by licensee headquarters, contractors, manufacturers and technical services. In addition ASN has no legal basis to conduct inspections before authorisation decree has been released, so impairing its ability to oversight siting activities.*	
(1)	**BASIS: GSR Part 1 para. 2.13 states that** *"The regulatory body shall be conferred with the legal authority to require an authorized party or an applicant, whether a person or an organization, to make arrangements to provide:* *a) All necessary safety related information, including information from suppliers, even if this information is proprietary;* *b) Access, solely or together with the authorized party or applicant, for making inspections on the premises of any designer, supplier, manufacturer, constructor, contractor or operating organization associated with the authorized party."*
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.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Certain decisions related to nuclear safety and radiation protection taken by ASN can be vetoed by the government.*	
(1)	**BASIS: GSR Part 1 para. 2.13 states that** *"The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making."*
(2)	**BASIS: GSR Part 1 para. 2.18 states that** *"To be effectively independent, the regulatory body shall have sufficient authority and sufficient staffing and shall have access to sufficient financial resources for the proper discharge of its assigned responsibilities. The regulatory body shall be able to make independent regulatory judgements and decisions, free from any undue influences that might compromise safety, such as pressures associated with changing political circumstances or economic conditions, or pressures from government departments or from other organizations…"*
R2	**Recommendation: The Government should take the appropriate measures to ensure that ASNs safety related decisions cannot be vetoed.**

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

In France, the prime responsibility for safety is assigned to the operator, which is an organization (nuclear facilities) or a person (other applications). The responsibility is assumed throughout the lifetime of the facility/activity and is not transferable. New authorization should be granted if the licensee changes.

The licensee should provide for the required technical capacities for the given activity. The licensee is responsible for the contracted organizations to comply with the regulations and should monitor their performance.

The regulatory body has the authority to supervise the responsible persons or organizations to verify compliance with stipulated regulatory requirements. This supervision does not relieve the licensee of its prime responsibility.

If the licensee of a radioactive source changes, it is mandatory to verify by the original licensee that the new one has the required authorization. This is an enforceable requirement by penalty.

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

The responsibilities and functions of each authority have been specified in relevant legislation. Regulations do not provide for coordination between the ASN and other authorities with responsibilities in nuclear or radiation safety, but several agreements have been concluded and documented by the ASN and the co-organizations to improve the coordination.

Concerning emergency situations the emergency response plan describes how the authorities cooperate. For transportation emergencies there is also a plan how the authorities coordinate in an accident situation. The ASN takes part in the assessment of the situation, assists other authorities with technical advice, communicate with the public and with international organizations.

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

The Government has established an effective system for protective actions to reduce radiation risks associated with unregulated sources and contamination from past activities or events. The following principles are applied in the legal framework: the polluter pays, prevent future pollution, identify, monitor and manage the impact of the pollution, put the polluted sites in a safe state, manage the sites in accordance with their future or current uses, retain a record of the pollution and of the remediation done in the past, and inform the public about the risks linked to these sites.

France has no exemption level for cleaning up contaminated areas. France has a doctrine to clean completely. If that is not possible, the decision will be made on a case by case basis. The purpose is to avoid any health effect.

In France, there is no periodic campaign for recovery of orphan sources.

ASN has set up several pluralistic working groups, to enable stakeholders to take part in the development of doctrines, the definition of action plans or the monitoring of their implementation. They involve stakeholders such as NGOs, trade unions, and elected representatives, on top of ministerial departments, licensees, and technical support organizations. One of these pluralistic working groups (CODIRPA) deals with the topic of preparation for post-accidental situation management. Based on the work of CODIRPA, ASN published in November

2012, the first elements of the national doctrine for post-accident management of a nuclear accident.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In France there are no periodic campaigns for recovery of orphan sources. While there is an oversight system of scrap yards larger than a 100 m^2, there is no comprehensive surveillance system for detecting orphan sources in all other places where they are anticipated to be found.*	
(1)	**BASIS: GSR Part 1 Requirement 9 states that** *"The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization."*
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.**

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

The French Government has made provisions for safe decommissioning of facilities, and management of spent fuel and radioactive waste.

The environmental code contains the strategy and main principles to be followed in this regard including responsibility of the producers, ban on disposal of foreign waste, reprocessing of spent fuel, and deep geological disposal as the management route for waste that cannot be disposed of in surface or near-surface disposal facilities. A national agency (ANDRA) independent of waste producers was created to be in charge of management and disposal of radioactive waste. According to the code, the Government has to submit to the Parliament, the national radioactive materials and waste management plan (PNGMDR) every 3 years, which is implemented by a decree. ASN provides advice to the plan from a nuclear safety and radiation protection point of view.

The envisaged time between final shutdown of the installation and its dismantling shall be as short as possible, while the final state reached on completion of dismantling must be such that it prevents risks or inconveniences considering the planned use.

The decommissioning of a basic nuclear installation is subject to prior authorisation from the government. Licensees and producers of radioactive waste and spent fuel have to assess the cost of decommissioning, of reprocessing of spent fuel, of long term management of waste, and establish reserves to cover the costs. Licensees and producers of radioactive waste have to submit every three years reports detailing their methods and hypotheses to evaluate this cost and these reserves. French law anticipates immediate decommissioning after shut down. The final state after decommissioning is required to be defined, but no interim targets during decommissioning are defined.

The Government has made provision for safe management of spent fuel. The French strategy is to reprocess the spent fuel from nuclear reactors.

In accordance with the Environment Code, Andra manages a "research fund" in order to finance research and development on deep geological disposal of high-level and intermediate-level long-lived radioactive waste. The fund is financed from “research tax” that is paid by licensees of BNIs.

1.8. COMPETENCE FOR SAFETY

Concerning BNIs, the ASN approves at the time of licensing the required competences of the licensees. There are no detailed requirements for the training programme of the licensees. ASN inspects and assesses the training activity of the licensees. ASN does not certify the operator, but checks the process of certification. ASN does not inspect the training itself, it checks if the process exists and is effective to train the operators.

The sufficient number of qualified personnel is required by law and assessed by the ASN as part of the authorization process.

France has detailed requirements on how to train inspectors, but non-ASN inspectors do not have specific training in nuclear safety.

The competence of IRSN is the same as ASN, but there is no uniform requirement for IRSN on what competences they need to have.

Environment Code includes only some general requirements for the operators to assure adequate qualification of personnel in their organizations for BNIs.

Labour Code includes specific requirements for operators in industrial radiography and requests a certification on the competence of personnel which is issued by IRSN

For medical facilities there are requirements in force, especially for radio-physicists.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no legislation in France to require building and maintaining technical competence of all parties (operators, licensees, authorities) involved in Nuclear Safety and/or Radiation protection, including definition of level of competence required arrangements to achieve it and mechanisms for periodic supervision of actual level of competence obtained.*	
(1)	**BASIS: GSR Part 1 para. 2.35 states that** *“The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety. Competence shall be built, in the context of the regulatory framework for safety, by such means as:* *a) Technical training;* *b) Learning through academic institutions and other learning centres;* c) *Research and development work.”*
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.**

1.9. PROVISION OF TECHNICAL SERVICES

Technical services essential for nuclear and radiation safety are available in France. The law requires the licensee to monitor occupational exposures, discharges to the environment and radioactivity in the environment nearby the licensed facility or activity. In addition IRSN performs a nationwide monitoring of air, surface water and food chain. In addition a national monitoring network has been set up and performing the monitoring of components of the environment.

ASN authorizes the laboratories of licensees to make the measurements required by law. Calibration of measurement equipment according to ISO requirements is anticipated by law.

1.10. SUMMARY

In France, supervision of the protection of the public and the environment against the dangers of ionizing radiation is performed by the ASN. The legal background for using the ionizing radiation is laid down mainly in the Environmental Code, Labour Code and the Public Health Code. ASN is importantly supported in its regulatory activities by its technical support organization, the IRSN. Together they have the appropriate resources for carrying out the current tasks involving authorization, inspection, review and assessment, and enforcement acts of nuclear facilities and activities.

The French framework enables the ASN and IRSN to perform the duties independently of the other Government organizations and interested parties. ASN cooperates with several agencies in France, mainly in the area of emergency preparedness.

The primary responsibility for safety is clearly stated to be assumed by the operators of the facilities and activities.

The French Government has made appropriate provision for the safe management of spent fuel and radioactive waste, and laid down the principles for decommissioning of nuclear facilities.

ASN and IRSN have the necessary competences for performing the supervision of nuclear safety and radiation protection.

Areas of improvement identified by IRRS team:

- Systematic incorporation of all fundamental safety objectives of the IAEA
- Provision of opportunity for ASN to inspect contractors of licensees
- Provision of independent decision making of ASN
- Re-enforcement of surveillance of orphan sources
- Provision of building and maintaining competence of all parties

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

France participates in all the relevant international conventions on nuclear safety, which are the Convention on Nuclear Safety, the Convention on Early Notification of a Nuclear Accident, the Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. France is also committed to work towards the full implementation of the Code of Conduct on the Safety and Security of Radioactive Sources through submission of written documents to the IAEA.

Participation and involvement in bilateral and multinational activities are also important to enhance safety thorough acquiring information on good practices or harmonized approaches. In that sense, ASN has signed bilateral cooperation agreements with many countries, currently with about 30 foreign regulatory bodies, and participates as a member in the activities of multinational organizations, such as IAEA, OECD/NEA, and MDEP.

ASN is involved in international peer reviews, not only receiving them but also participating in them. ASN is contributing to the international peer reviews especially through receiving the first full scope IRRS mission in 2006 and having its staff take roles as team leaders or deputy team leaders in many IRRS missions.

To make the French legislative and regulatory framework applicable to nuclear facilities and activities more effective for continuous improvement of the safety, ASN uses IAEA safety standards as a basis for the development of its national regulations and guides. Even though ASN recognizes that the process is not sufficiently formalized to fully follow its evolvements and the general review of current nuclear safety regulations, as well as the transposition of the European directive on basic safety standards, it is an opportunity to update regulations and guides.

Commitments by the commission are very important and while there are resource constraints, a strategy for international cooperation is formulated and approved by the commission each year so that necessary supports in international activities are realized.

In addition to the above, the IRRS team acknowledged an ASN contribution to IAEA safety standards regarding transportation. ASN has taken a leadership role to bring the best practices of the European Association of Competent Authorities to the awareness of TRANSSC. In particular, ASN staff proposed to develop a new IAEA Safety Guide based on the Package Design Safety Report in ASN Guide No. 7, “Transport of packages or radioactive materials for civil use on public roads” which provides detailed guidance to applicants for the format and content of the safety case documentation.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Based on a Decree established in 2012, licensees are required to report operational events to ASN as soon as possible after they occur. However, which events and when to be reported is not specified in the regulations. ASN provides guides to licensees and is now working to establish these guides as legally binding ASN decisions. This issue is referred to in chapter 9 of this report.

ASN requires licensees to implement an integrated management system and to collect experience feedback from the operation of is facilities and other facilities in France. Licensees are also required by ASN to extract lessons from significant events that occur abroad, particularly from the reports in the IRS database of IAEA and NEA. To share operating experience within the

industry, seven permanent groups are led by ASN. ASN also holds regular meetings with licensees and IRSN to share information on operating experience.

ASN has a section responsible for the collection of operational experience in France and the preparation of internal procedures. The significant events reports and the periodic assessments submitted by the licensees provide the bases for the assessments by ASN. In order to prepare conclusions based on operational and regulatory experience feedback, ASN requests opinions and recommendations from seven advisory committees (GPE) which consist of experts in various areas (reactor, waste, nuclear pressure equipment, etc.).

In the case of international operational experience, responsible ASN staff collects data coming from IRS database and/or from USNRC releases, through attending WGOE/NEA meetings, etc. and disseminates the information to relevant ASN staff members. ASN requests IRSN to review international operational experience and present the results of their assessments. International operational experience is also discussed during the meetings with licensees and IRSN.

In terms of information dissemination, ASN publishes the information on operating experiences on its web-site and shares it with international community through the participation in the international forums such as International Reporting System (IRS) organized by IAEA and NEA, Working Group on Operating Experience (WGOE)/NEA and so on.

2.3. SUMMARY

France fulfils its respective international obligations and participates in the relevant international arrangements. ASN is actively involved in bilateral and multinational activities and devotes adequate resources into those activities. Although ASN is making significant contributions to international nuclear safety community, ASN recognizes that there are still some rooms for improvements through implementing periodical reviews of evolutions in international standards so that ASN can detect needs for updates in French regulations and guides.

ASN requires licensees to report operating experiences and establishes various arrangements to analyse and to extract lessons learned from them. Opportunities exist for improvements by ASN by internally implementing more formalized and systematic approaches regarding operating and regulatory experience from other countries.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The Environmental code (previously the Act on transparency and security in the nuclear field, TSN Act) provides the legal provisions regarding the overall framework for regulation of nuclear safety and radiation protection and ASN is the French regulatory body. ASN is not within any ministry but is an independent State Authority. ASN is not the competent authority for security and physical protection of nuclear installations.

The Government is responsible for general nuclear law (decrees, ministerial orders) and takes the main decisions regarding nuclear installations (e.g. creation authorization). ASN makes regulatory decisions implementing decrees and ministerial orders and controls the nuclear installations and activities. Procedure ASN/ORG/01 describes the rules for making decisions within ASN.

ASN is managed by a board of 5 commissioners created by the Environmental code. ASN Commission defines ASN general policy, takes the major decisions and adopts public statements on key issues within ASN competence. Commissioners are appointed for six years and the term cannot be renewed.

ASN has approximately 470 staff (240 in the headquarters and 230 in 11 regional offices). There are also 400 experts employed to support ASN within the IRSN (Institute for Radiation Protection and Nuclear Safety), which is ASN's main TSO.

ASN's organisational structure divides its activities between its central HQ and the regions, and the responsibilities of the latter may differ depending on whether there are nuclear facilities in the region. Each regional office defines its own operating plan within the framework of ASN's national orientation document.

Regional offices have the right to authorize routine BNI modifications and they perform most of the inspections. Regional offices can be supported by the headquarters and IRSN. Consistency of the functions between different regional offices is discussed in the meetings with the heads of regional offices and when analysing inspection reports. ASN budget is part of the state budget. It is the subject each year of a proposal from ASN to the Government before the Government defines a draft State budget which is submitted to the Parliament.

Regulatory decision-making takes place throughout ASN's organisation. The Government reserves the right to make the most important decisions to itself, for example, granting licences and the start of decommissioning. ASN's regulatory powers are vested in the Commission, and it delegates many of these to lower management levels in accordance with their significance.

A number of routine working level regulatory decisions are promulgated by letter from the Regional Representatives. These officials only concern themselves part-time (~10%) with nuclear and radiation safety matters. However, the ASN staff in regional offices work full-time on these matters and are not diverted onto other work by the Regional Representatives.

The Regional Representatives may refer decisions to ASN HQ if they consider it necessary. This system creates a potential for inconsistency, so the degree of central oversight was explored. It appears that Regional Representatives rely on their own judgement on whether they should refer issues to HQ, and central oversight is limited to post-decision audits of decisions rather than a system that informs HQ of proposed decisions prior to their promulgation.

In this respect, the system by which the Commission and Executive Committee determine whether delegated decision-making powers are being exercised appears weak and, as described earlier, has the potential to create inconsistencies.

With respect to resources, the costs of ASN and IRSN are met by the State budget. The State separately imposes a tax on BNIs (the BNI Tax) which exceeds the combined costs of ASN and IRSN. ASN has recently been somewhat successful in seeking some increased resources to meet some workload demands.

On the basis of its legal duties, regulatory responsibilities and recruitment needs, ASN established a human resources plan. This plan was discussed through the annual budgetary process with the French ministry of budget. BNI licensees pay a tax which exceeds the combined costs of ASN and IRSN. This income goes to the general state budget and only the ASN costs agreed by Government are reimbursed.

The IRRS team has noted that ASN's workload is forecast to increase significantly in the next few years. The government has provided ASN with a budget increase for 2015 that is more generous than the norm across the French civil service. However, this only partially reflects the anticipated increase in future workload, so ASN will have to make compromises in its plans for future regulatory oversight. If not carefully managed, this shortfall could have a negative impact on the effectiveness of ASN's future regulation.

These might include:

- a systematic analysis of the resources necessary for ASN to both meet its legal duties for regulation and to undertake discretionary activities that enhance nuclear and radiation safety;
- organisational changes to enhance efficiency;
- alternative means of cost recovery by the regulatory body, for example the direct recovery of costs from the licensees as used in a number of other countries;
- setting out ASN's prioritisation of regulatory activities, so that it is clear which of these will be progressed and which might have to be delayed or deferred in different funding scenarios.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team has noted that ASN's workload is forecast to increase significantly in the next few years. The government has provided ASN with a budget increase for 2015 that is more generous than the norm across the French civil service. However, this only partially reflects the anticipated increase in future workload. If not carefully managed, this shortfall could have a negative impact on the effectiveness of ASN's future regulation.*	
(1)	**BASIS: GSR Part 1, Requirement 3 states that** *"The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities."*
(2)	**BASIS: GSR Part 1 Requirement 16 states that** *"The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
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.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A number of routine regulatory decisions are made by the Regional Representatives, who have more responsibilities than nuclear and radiation safety matters. They may decide to refer decisions to ASN HQ, but use their own judgement on this which creates a potential for inconsistency. ASN central oversight is limited to post-decision audits of decisions rather than a system that informs HQ of proposed regional decisions prior to their promulgation. As a result, the potential for inconsistency may be managed by requiring decisions that might more appropriately be made at the regional level to be taken by ASN HQ.*	
(1)	**BASIS: GSR Part 1 Requirement 16 states that** *"The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities."*
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.**

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

ASN is legally independent in its safety related decision making and has functional separation from state entities responsible for promoting nuclear energy. Independence is enhanced by ASN having the status of an independent administrative authority.

The question of effective regulatory independence was explored. The Commissioners are appointed separately by the President of the Republic, President of the Senate and President of the National Assembly, and must have relevant competencies as set out in the TSN Act Art. 10. They are placed under a duty to "exercise their duties entirely impartially without receiving any instruction from the Government or from another person or institution" (Art. 13). Art. 22 also requires Commissioners and other ASN employees to not put themselves into positions that could compromise their independence. ASN is preparing a position code on ethics to support this measure.

Membership of the ASN Commission is incompatible with any professional activity, any elective mandate and any other public employment. On their appointment, ASN Commission members must make a declaration of the interests they hold or have held during the previous five years in the fields within ASN's competence. The nuclear safety authority resolution 2010-DC-0195 of

19 October 2010 establishing the Nuclear Safety Authority's rules of procedure sets out the ethics rules. A more detailed code of ethics is being prepared by ASN.

The independence of regulatory decision-making is also strengthened by the publication of ASN's opinions and in common with other civil servants; there are restrictions on staff transferring from the regulatory body to licensees' organizations.

The Chair of the Commission reports to Parliament in a number of ways: to formally present ASN's Annual Report and answer questions; and to provide information on specific topics, e.g. budgets.

There is a generic French rule for civil servants including ASN staff that they cannot work for licensees within three years of leaving the civil service. However, licensee staff may be recruited by ASN without such a delay. The appointment of Commissioners from licensees' organizations is not explicitly prohibited either, but political considerations might exclude this in practice.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ASN Commissioners are appointed separately by the President of the Republic, President of the Senate and President of the National Assembly, and are placed under an explicit duty to "exercise their duties entirely impartially without receiving any instruction from the Government or from another person or institution". There are also duties on the Commissioners, members of Standing Committees and ASN employees, which are elaborated in Ethics Codes, to not put themselves into positions that could compromise their independence. ASN inspectors must individually swear that they have no financial interest or stake in licensees, to demonstrate their independence.*	
(1)	**BASIS: GSR Part 1 Requirement 17 states that** *"The regulatory body shall perform its functions in a manner that does not compromise its effective independence."*
GP2	**Good Practice: ASN Commissioners, members of Standing Committees and staff are placed under explicit duties to act impartially and to declare that they have no interests that could compromise this.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

ASN has an organisational structure and has identified the specific skills and competencies required of staff within the posts in this structure. It has a structured training programme to ensure that staff is capable of properly fulfilling their roles and responsibilities.

However, ASN appears not to have a human resource plan in the form of a single document underpinning this structure, and the rationale for the organisational structure is consequently unclear. This makes it difficult to determine whether ASN has a sufficient number of staff for it to meet its regulatory duties. The bid for more staff appears to be based upon a preliminary assessment for post needs within the existing organisational structure in response to additional regulatory tasks. ASN might consider performing an analysis of the existing structure to determine whether a different structure and way of working would enable responsibilities to be discharged with more limited resources.

In common with other civil servants, ASN staff is expected to move between posts and organisations relatively frequently. However, the specialised nature of ASN's regulatory responsibilities means that staff needs more intensive training than in other parts of the civil service. This results in a relatively low ratio of time in post when an inspector is fully trained and

working effectively to time spent training. Although ASN has been able to extend the time inspectors spend in post by a year to compensate for this, it is unable to change the general policy. It is consequently important for ASN's training and staff succession arrangements to be well-planned and effective.

ASN's training programme has recently been updated. Documents setting out the strategy for this and improvements anticipated were requested. ASN staff qualifies as inspectors after completing basic training.

ASN human resources management aims to give the required competencies and necessary skills to each ASN department according to their needs and tasks to conduct. ASN's training program is based both on general and technical courses, some of which are mandatory depending on the area to be qualified. According to their position and the facilities under their supervision, staff will follow specific courses, firstly to be qualified as inspectors.

When a post is created, the service head sets out in a post-profile the missions, the context and required competencies. Competence requirements are related to the training course for accreditation and the acquisition of necessary professional experience. Qualification may be given in the following generic competence areas:

- nuclear safety,
- radiation protection,
- transport,
- pressure equipment.

ASN allocates more than 4500 days per year for training.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ASN does not have a formal procedure or tools for planning its long-term staffing, succession and competency needs. The relatively high level of staff turn-over within ASN makes the lack of a formal procedure a potential vulnerability.*	
(1)	**BASIS: GSR Part 1 Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
(2)	**BASIS: GSR Part 1 Para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(3)	**BASIS: GSR Part 1 Para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
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.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

ASN engages support from 3 types of organisation: IRSN for the majority of its technical support, Standing Committees, and more diverse external advice. The framework for IRSN support is set out in a 5 year Convention, and details are negotiated annually and agreed in a Protocol. ASN incurs no charges for IRSN support, but has to agree contracts and pay for more diverse advice. It has established a framework with the latter organisations to simplify this process.

To make decisions, ASN can seek advice from 3 categories of experts as needed: IRSN, standing committees of experts and other external expert organizations. For ASN, IRSN is the main TSO. Its advice is sought on most of the topics for which ASN needs an expert opinion. IRSN gives ASN about 600 opinions a year. Areas of expertise for which ASN may request IRSN advice are outlined in the five-year agreement and defined in more detail in an annual protocol.

IRSN is a public body created by statute and reports to 5 Ministries. The statute establishing IRSN also gives it a responsibility to provide technical support to ASN. Of its budget of E295 million, 40% is spent on research, representing a declining proportion of the total. Its role is to use scientific and technical knowledge to make balanced judgements and provide informed opinions, and its research activities support this objective. ASN and IRSN jointly make the case to Parliament for funding of its support activities.

The priorities and work schedules for IRSN's work programme to support ASN are agreed between the two organizations, with ASN making the final decisions. ASN defines the advice sought through letters specifying the topic, meeting requirements, timescales for reporting, and the questions to be answered. In response, IRSN may provide advice on methodologies, technical answers and recommendations for regulatory action.

ASN reserves the right to take regulatory decisions itself, notwithstanding opinion from IRSN. An example of ASN rejecting an IRSN recommendation in Fukushima-related issues was given. For transparency, both the ASN decision and IRSN opinions may be published, and reasons for differences are recorded. Meetings are held on a regular basis at various management levels up to and including the Director General level to review progress and provide feedback to IRSN.

IRSN's opinions and reports are developed and endorsed through an internal management system, to ensure that they represent corporate positions rather than those of individuals, and are of appropriate quality. As mentioned earlier, IRSN reports are not formally accepted by ASN, as they represent advice. ASN may take a different position to that proposed by IRSN and if so, this is set out in feedback to IRSN. ASN also completes evaluation (customer satisfaction) forms for the reports that IRSN submits. A document common to both management systems sets out this process.

IRSN receives requests for opinions from ASN Departments or Regions. The lead entity for a request depends on its safety significance and whether it is a generic issue or site-specific, and is set out in a Quality Management Note.

ASN and IRSN work as partners and as both organizations and their roles are established by statute, the structure of the overall regulatory system that they comprise together is effectively fixed. As noted above, their funding bids to Parliament are also linked. They were asked by the IRRS team whether a different relationship and structure might bring benefits. IRSN noted that this question has been discussed at high level in the context of the new Energy Transition Act. However, the current system has certain benefits; for example, the dissociation of IRSN from ASN's regulatory decisions allows it to freely challenge regulatory positions if and when new knowledge emerges. In addition, improvements have been identified in relation to the transparency of IRSN opinions and ASN's oversight of IRSN's technical expertise.

A further benefit of the current arrangement is that IRSN's research interests enable it to offer employees a broad scientific career, which assists in the recruitment of specialists. It may also be seen as a stepping stone to careers with either the licensees or regulator.

IRSN may undertake work for licensees as well as providing support to ASN. An ethics code applies to staff so that those working for licensees do not give opinions on the same topics to ASN.

The capability of ASN staff to judge the technical advice given by IRSN and act as intelligent customers was explored. Inspectors' post-profiles do not require an explicit capability to do this, but the technical competencies required implicitly provide this.

For authorizations, ASN checks first whether the information submitted by the authorized party is complete and of a sufficient quality. Once the TSO advice is available, ASN defines its position based on this advice. ASN can also disagree with IRSN's position but then the reasoning has to be documented in the decision. For inspections, IRSN may be invited to take part in the preparatory meeting and to participate in the inspections. ASN prepares the inspections reports and submits the letters to the licensees.

The Standing Committees and IRSN both provide advice to ASN, but the most important topics are reserved to the Standing Committees. The latter base their considerations on IRSN advice, but provide an additional level of scrutiny and this represents an application of the graded approach.

The advice sought from the Standing Committees is defined by ASN and although they may in theory propose additional topics for consideration, this has to be agreed by ASN and rarely happens. The advice sought is invariably on technical rather than policy issues, in keeping with their different technical scopes. The Standing Committees' discussions are based upon and limited to the reports submitted by IRSN. The members' deliberations focus upon areas of disagreement between the licensees and IRSN. They do not engage other external experts or establish working groups to assist them with this activity. However, the composition of the membership brings a significant diversity of expertise to bear on the issues discussed.

The Standing Committees finally prepare a short report on the topic discussed, with recommendations. This report is also based upon a draft provided by IRSN, although it may be heavily modified. The recommendations are quite specific, but although neither ASN nor licensees are bound by them, ASN usually accepts them. When it does not, it gives the reasons. The reports and recommendations are published once ASN has determined its own position.

The predominance of IRSN in the Standing Committee processes and exclusion of other expert organisations may limit the diversity of technical input to the Standing Committees' deliberations, apart from the technical expertise of individual members.

Great emphasis is placed upon the members acting impartially and as individual experts, rather than representing their employers or parent organisations.

The members of Standing Committees are experts drawn from a diverse range of organisations, including licensees and NGOs. A code of ethics for members was introduced this year which requires potential conflicts of interest to be declared and ASN will maintain a register of these interests. Where the perceived conflict is low, a member may participate in a meeting but not vote. If the perceived conflict is high, the member may not participate in the meeting.

ASN has 7 permanent advisory committees. Formed around specific topics, they gather experts appointed on a personal basis because of their competence. They come from the operators concerned by the issues discussed, expert bodies, academics and associations, including also foreign members. They are provided with reports presenting the results of analyses carried out

most often by IRSN, but also by ASN, and they issue advice and recommendations. ASN is always making the final decision concerning the issue but advisory committee statements are also published.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There is a wide range of interactions between ASN, the licensees and other bodies, and the arrangements are set out in SMQ/REL/101. Although specific periodicities are set out for the different types of meeting, there is flexibility to vary these as required by the circumstances.

ASN staff said that the discussions with licensees are open and frank and there may be robust debate prior to ASN taking decisions. Licensees' behaviour post-decisions varies, with some accepting the decisions taken and others sometimes disputing them resulting in delays to their implementation. On occasions, licensees have sought to appeal to the Commission, and indeed some changes have been agreed as a result.

ASN maintains regular relations with the main nuclear licensees and also develops relations with the users of ionising radiation in the industrial and health sectors. Document SMQ/REL/01 describes the main meetings with stakeholders on national level.

ASN inspectors receive training in various types of communication, including writing for publication (all inspectors), media training (managers), and dealing with a range of licensee staff behaviours. The latter is noteworthy as it includes simulations of engagement in different circumstances.

The objective of ASN's relations with its professional audience is to enhance knowledge of the technical, organisational and human aspects of the regulations and nuclear safety and radiation protection culture. In this respect and in addition to its website www.asn.fr, ASN produces publications intended specifically for them and organises or takes part in many symposia, seminars and other events, in order to:

- raise the awareness of the professionals with regard to the responsibilities and implications of radiation protection;
- disseminate the regulations and promote their implementation;
- encourage the notification of significant events and experience feedback.

The IRRS Team leadership met with senior EdF managers to discuss engineering and inspection oversight. The EdF managers asserted their commitment to improvement of nuclear safety and confirmed that it meets regularly with ASN staff.

IRRS SITE VISIT TO AREVA

On November 20, 2014, the IRRS Team Leader (TL), Deputy Team Leader (DTL) and IRRS IAEA Team Coordinator met with the Chief Operating Officer of AREVA and members of his staff. AREVA is a French company that manufactures major components for constructing new build nuclear power plants world-wide and large replacement reactor components for EDF and other international operators. In addition, AREVA also operates the AREVA Fuel Facility at La Hague, which is regulated by ASN.

During the meeting, discussions were centred on standards of nuclear safety at the La Hague facility. In addition, the relationship between IRSN and AREVA was discussed. This matter was of relevance, because IRSN provides technical services to AREVA as well as serving as ASN's TSO. Specifically the TL probed the measures in place such that there were processes to ensure no conflicts of interest existed by IRSN providing services to both parties.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The stability of the regulatory system was explored in the context of post-Fukushima safety improvements required by ASN. The Commission issued new Complementary Requirements in 2012 and followed these with a Resolution setting out more detail. The latter is legally binding on the relevant licensees.

It was confirmed that ASN followed established practice in issuing these new requirements and these actions consequently represented a predictable response to new and emerging information. At the time that they were issued, there was no mandatory requirement for public consultation but a recent change in the law has changed this. Any proposed legal change that may have an environmental impact must now be subject to public consultation. The required period for this may however be rather short, being a minimum of 21 days.

With respect to the authority of individual inspectors for making regulatory decisions, it was confirmed that proposals must always be agreed within the management line before they may be implemented.

ASN's most important decisions (e.g. mandatory resolutions) are taken by the board of Commissioners, in a collective way. During the preparation of decisions to be taken by the board of Commissioners, ASN must collect observations of licensees on the draft decisions. The regulatory body should also consult the public on its draft decisions that have an impact on the environment.

There are rules of signature delegation within the ASN following the principle of using a graded approach. Expert reviews are referenced in ASN decisions and are recorded. Differences between IRSN expert opinions and ASN decisions are documented.

Inspections are in general conducted with at least two inspectors. They come from either the same regional division, a department and a regional division, or two different regional divisions.

Many actions are performed by ASN through "coordination meetings" bringing departments' and regional divisions' management together. These meeting enable the sharing of good practices and the feedback of issues to headquarters.

3.7. SAFETY RELATED RECORDS

ASN has a central IT system for storing records. Each Department and Division is responsible for tracking actions resulting from inspections and a tool is provided for this. The IRRS Team was informed however that the application of this is inconsistent and is being improved and it is sometimes difficult to demonstrate that past issues have been closed. An improved tool to track issues is being developed.

ASN's management system specifies requirements for record keeping relating to the safety of facilities and activities under its control. ASN has a document management system where e.g. all the authorizations, inspection reports and handling of event reports can be found. Each authorization or inspection has an information sheet collecting all the generic information related to that project and all relevant documents are linked to this.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Follow-up of ASN requirements and licensees' commitments is already carried out through monitoring of licensee commitments and inspections, but it is done with different follow-up systems within the headquarters and different regional offices. Currently there is not a harmonised system which could be accessed by all the staff and used to check the status of different requirements. ASN has recognized the need to strengthen its follow-up of ASN requirements and licensees' commitments.*	
(1)	**BASIS: GSR Part 1 para. 4.60. states that** *"The regulatory body shall confirm that the authorized party has effectively implemented any necessary corrective actions."*
(2)	**BASIS: GSR Part 1 Requirement 35 states that** *"The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities."*
(3)	**BASIS: GSR Part 1 para. 4.65 states that** *"The regulatory body shall use such records in support of its regulatory functions and to support the enforcement of regulatory requirements."*
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.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

ASN is responsible for the implementation of specific communication tools (website, Contrôle magazine, Annual Report on Nuclear Safety and Radiation Protection in France). ASN also submits key resolutions on BNI as well as resolutions on nuclear activities likely to have an impact on the environment to public consultation via the internet. ASN publishes the most important decisions on its website and the related IRSN and standing committee opinions. ASN also reports to the Parliament.

ASN is under a legal duty to provide information to the public. There is also a legal duty for licensees to provide the public with information, so that if ASN receives an inquiry, it may refer the requestor to the licensee for it to provide the information directly.

France has a national High Committee for Transparency and Information on Nuclear Security, which was created by statute as an independent consultative body. Its 35 members are appointed for a period of 6 years and they comprise a wide range of senior representatives selected on the basis of their scientific and technical competence, and it acts as a forum for high level debate on a variety of issues. It issues opinions and reports and it provides public information at the national level including an annual report that it publishes on its website. Although it cannot place actions on other bodies, its status is such that they are effectively bound to respond to its findings. Some IRRS team members met with the first President of this body and they considered the discussion reinforced the ARM.

There are also Local Information Committees (CLIs) which provide forums for debate at the local level. Their membership comprises local representatives such as Members of Parliament for the area, local authorities, etc. As well as debating matters of local interest or concern, the CLIs

may engage consultancy services to provide them with information to support their discussions, for example epidemiological studies and environmental surveys. A radiological survey performed for the Gravelines CLI was cited as an example. Funding for these activities is provided on a shared basis by ASN and the local councils.

For each NPP, there is a local information committee (CLI) which is responsible for keeping the public informed on nuclear safety, radiation protection and impact of the nuclear activities on persons and environment. The CLI is composed of representatives of local councillors and deputies, environmental protection associations, economic interest groupings, plant employees' trade unions, the medical professions. It gets funding from ASN and government for making expert assessments, epidemiological studies and measurements or analyses in the environment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ASN submits key resolutions to public consultation via the internet. It publishes the most important decisions on its website, together with the related IRSN and advisory committee opinions that informed its decision. The IRRS Team noted that ASN has established many processes for engaging with its stakeholders, at the government level, at the level of the licensee and with the public. Particular examples commented on by the IRRS Team include the process to involve stakeholders in the reduction of unintended exposures in the medical field (Chapter 11, 11.1; the support provided to CORPAR, the network of PCRs to share experience (Chapter 11, 11.2; the public communication undertaken by ASN following the Fukushima accident (Chapter 13, 13.1).*	
(1)	**BASIS: GSR Part 1 Requirement 36 states that** *"The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."*
(2)	**BASIS: GSR Part 1 para. 4.27 states that** *"The regulatory body shall also inform and consult interested parties in relation to the basis for such proposed changes in regulatory requirements."*
(3)	**BASIS: GSR Part 1 para. 4.61 states that** "*The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience."*
(4)	**BASIS: GSR Part 1 para. 4.66 states that** *" The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and for informing the decision making process.*
GP3	**Good Practice: ASN has incorporated measures to achieve transparency, effective public communication and engagement of stakeholders across all its activities and with all its key stakeholders. The IRRS Team considers that its efforts in this regard are exemplary.**

3.9. SUMMARY

ASN has a mature and effective organizational structure, and its independence in regulatory decision-making is clearly established and safeguarded. Great emphasis is placed on the duty of impartiality placed upon Commissioners, Standing Committees and ASN staff, which are set out in Ethics Codes. ASN takes advice from a diverse range of Standing Committees, the IRSN and other bodies, and this advice is published so that the decision-making process is transparent to the public.

The regulatory system is stable, generally consistent, and safety-related records are preserved. Some good practices and a few areas for improvement have been identified.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

The requirement for establishing a management system by ASN originates in a decision, which was approved by the Ministry of Environment in December 2010. This decision does not indicate any specific standards to be met or used for developing the ASN's management system.

The ASN management system has evolved over time and the first version of ASN's integrated management system, documented in the management system manual, was issued in 2012. The documentation of the management system consists of the Management System Manual, notices (process maps), procedures and tools (guidelines, templates, etc.). All these documents are available in an electronic format and can be accessed by any ASN staff member (headquarters and regional offices) on the intranet.

The management system manual states that ASN applies a quality approach, based on international standards, including GSR Part 1, GS-R-3 and ISO 9001. A revised quality policy declaration for the period covering 2013 to 2016 was issued in 2013. It addresses the development and promotion of a quality culture among all ASN staff. It promotes improvement initiatives that can contribute to the effectiveness of ASN's quality management system (SMQ), as well as reporting and taking advantage of opportunities to benchmark SMQ.

The technical and legal requirements related to ASN's operation are collected in lists of documents that are accessible on the intranet. These lists are specific to nuclear safety, radiation safety and legal requirements. The most recent revisions of these documents were completed in 2011, 2012 and 2014, respectively. The IRRS team noted that the process descriptions do not identify the relevant IAEA Safety Requirements and they are not identified in the management system manual.

The ASN Quality Manual indicates that the responsibility for the development and implementation of the management system is assigned to the ASN Quality Manager, who works in the management and expertise office (MEA). Currently ASN is preparing a letter to formally nominate the ASN Quality Manager. This issue has also been identified by ASN in its self-assessment. The person responsible for the management system is supported by a network of 18 process leaders (pilots) and about 21 quality coordinators. Their roles are described in a quality management procedure.

The 12 key ASN processes identified in the quality manual are divided into three categories: management, core and support processes. The core processes are identified as: regulate, authorise, monitor, manage emergency situations and inform the public. The regulatory review and assessment is not identified as an ASN key process and there is no description or documentation describing this regulatory function. Some aspects of the review and assessment regulatory function are described in quality documents related to other core processes (e.g. in authorization process for review of modifications). For example, the integrated safety assessment process, which is required by GSR Part 1, para 4.46, is not described in the management system documentation but is conducted by ASN divisions based on a request issued annually in a letter by the senior management. ASN has identified the need to describe the core regulatory function for review and assessment, which was also identified by the self-assessment. The IRRS team was informed that this will be addressed starting in 2015, as part of a new project; a general note and specific documents for facilities and activities will be developed.

There are several support processes that are not included in the management system and are not linked with its documents. For example, human resources processes are described in a separate

intranet portal and do not follow the same structure as the other processes described in the management system manual.

The management system manual does not globally address the interfaces between ASN processes, but the IRRS team was informed that ASN has started a project for development of an overall process map, in which the interfaces between core processes will be identified. This should be completed, in the future, for all ASN processes.

The IAEA safety standard, GS-R-3, requires the management system to be used to promote and support a strong safety culture. While the IAEA definition of safety culture is noted in the ASN general note on Quality (Implementing continuous improvement), safety culture is not explicitly addressed in ASN's management system and there is no process description on how the organization will ensure a common understanding of the key aspects of regulatory safety culture. The IRRS team noted that this issue was also identified in the self-assessment and ASN is currently planning to address safety culture in the organization through a new project; a draft document explaining the approach on how safety culture should be integrated in ASN processes has been developed.

Grading of the management system is reflected in the documents supporting its implementation, in which, for example, the extent and frequency of regulatory inspections for fuel cycle facilities and nuclear power plants are described. These are based on a number of criteria, including consideration of the magnitude of potential impact (risks) associated with nuclear and radiation safety. The application of a graded approach for authorization is not described in the existing process documents because these documents have not been recently revised.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ASN has not conducted a systematic analysis for identifying all the processes needed to deliver the regulatory mandate and does not have an overall process quality plan indicating which processes are still to be developed and the associated timelines and milestones. This is needed in order to ensure the integrated management system and its processes address all the relevant requirements, as well as for providing adequate resources for implementation. There are several more detailed observations concerning the comprehensiveness of ASN's management system in the Chapter 4.*	
(1)	**BASIS: GS-R-3 Para. 2.1 states that** *"A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement"*
(2)	**BASIS: GS-R-3 Para. 2.8 states that** *"The documentation of the management system shall include the following:* - *The policy statements of the organization;* - *A description of the management system;* - *A description of the structure of the organization;* - *A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;* *A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GS-R-3, Para. 5.1 states that** "*The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved.*"
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.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Safety culture is not being addressed explicitly in ASN's management system. ASN is currently planning to address safety culture in the organization through a new project.*	
(1)	**BASIS: GS-R-3 Para. 2.5 states that** *"The management system shall be used to promote and support a strong safety culture by:* - *Ensuring a common understanding of the key aspects of safety culture within the organization:* - *Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;* - *Reinforcing a learning a questioning attitude at all levels of the organization;* - *Providing the means by which the organization continually seeks to develop and improve its safety culture."* *See also GS-R-3 Sections 3.13, 6.2 and 6.3.*
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.**

4.2. MANAGEMENT RESPONSIBILITY

The ASN management demonstrates its commitment to the implementation and improvement of the management system by fulfilling specific roles, such as lead (pilot) and participant in the relevant activities, including self-assessment, management reviews, internal audits, etc. ASN has issued a Quality Notice to describe and support the implementation of continuous improvement in the organization.

Stakeholders' satisfaction is assessed trough an annual survey conducted by an external organization and the results are reported to the Commission. In addition, inputs from interested

parties are discussed and considered, as appropriate, as part of core regulatory processes, such as development of regulatory documents, meetings with ASN management, etc. An annual plan for interactions with various stakeholders, such as operators, academic institutions, other governmental entities, foreign organisations, etc. is developed, implemented and monitored.

ASN organisational policy was established by the Commission and is reflected in the management system.

The planning process, which is developed based on a multi-year strategic plan, is described in the management system manual and associated operational guideline. Specific objectives, targets and priorities are established, monitored and reported to senior management and as part of the ASN annual report.

4.3. RESOURCE MANAGEMENT

The management system manual and its documentation do not include a description of the process describing how the organization's human resources are determined and how the needs for additional resources are identified. The general note for human resources, which is part of the management system documentation, indicates that each organizational unit has to formalise its needs for HR, but the method on how this should be done is not described. The IRRS team reviewed a note prepared by one ASN division containing an analysis of the adequacy of its human resources. This analysis was based on the activities to be carried out by divisions and resulted in a request for additional staff, which was submitted for approval to the next level of management. Expending this approach and applying it in a consistent manner at ASN's level would support a human resources needs-analysis for the entire organization, and could be considered for implementation (see also Section 3.3).

The management system manual and its associated documentation do not contain guidance or make reference to other documents describing the contents of job descriptions. Some information provided, e.g. for inspectors' qualification in the HR dedicated portal on Intranet, is not linked to the management system.

The generic human resources process indicates, at a high level, that specific tasks have to be completed by a departing staff member. Specific information on ASN knowledge management programme (e.g. how knowledge is identified, analysed, recorded, etc.) is not included or described in the management system.

The IRRS team was informed that, in addition to the MEA office dedicated staff, process leads and quality coordinators are expected to dedicate time to quality management related issues; for example, 10% for the quality coordinators. The allocation of time for quality management related activities appears to be sometimes a challenge, especially due to the heavy workload in specific circumstances (e.g. after Fukushima Daiichi accident). The postponement of the planned external audit of IRSN, which was planned by ASN, was due to lack of resources.

4.4. PROCESS IMPLEMENTATION

ASN receives feedback on the operation of its management system through themed and periodic reviews conducted by each of its entities. Proposals for improvements to processes may be triggered by these periodic activities or via improvement sheets initiated by inspectors and agreed by Unit Heads. The process for modifying a process document is set out in the management system. Generic processes are developed by ASN HQ Departments, but process ownership is allocated to individual regions. The central Department drafts the process, which is then further developed by agreement with the responsible region. The responsible region then consults other regions before the process is agreed and promulgated.

Each region develops its own "applied processes", which complement the generic ASN processes with local details. Regions are not permitted to alter the requirements of the generic processes, only to add additional requirements that are needed locally. Regions may not initiate new processes or the revision of existing processes.

ASN has identified and documented a number of processes and sub processes, which are available to all employees on the intranet. The development of new generic processes or the revision of existing ones may be initiated by any employee using the improvement sheets. The development or revision of a generic process or sub process is managed by the designated process lead (pilot) based on an internal procedure. Various ASN organizational units may be involved in the development of a generic process.

When a national quality document is approved, the QA Manager informs ASN staff trough a newsletter (Point Qualité), identifying the potential implications for operational aspects, and makes the new or revised document available on the intranet. In addition, the tool used for self-assessment will be updated with the new requirement document.

The management system documentation contains templates for notices (process maps) and procedures, but not for guidelines. During the self-assessment, ASN has recognised that there is a need to revise the existing documents in order to bring them in line with the requirements of GS-R-3 (e.g. par. 5.4).

All quality documents have to be revised every five years, based on a quality generic procedure. The IRRS team noted that there are differences in the format and content of various documents within a same category. It was explained that this is due to the fact that some of them are "old" documents and will be updated during the regular revision process.

The IRRS team was informed that consistency between the processes used by various organizational units and divisions is assured by the fact that the specific requirements for a process are defined in the generic process description, and that these are used during the cross-cutting audits. There are also periodic reviews for processes, conducted by the process leads; the results are presented to the quality coordinator and to the senior management, as appropriate. For example, the inspection process is reviewed each year; it is planned to apply this approach to the authorization process in the near future.

The ASN support processes contain a number of generic processes, as identified in GS-R-3, but do not provide information on purchasing and management of organizational changes. However, the building relationships process describes the expert evaluation process, which is mainly addressing the relation with IRSN.

Regarding organisational changes at an organizational or divisional level, the unit head defines and implement the necessary changes in his/her unit, taking into consideration professional union aspects. At the organizational level, the structure is validated by the Commissioners; however, there is no process describing how organizational changes are evaluated, classified, implemented and monitored.

The IRRS team noted that the process for procurement and, in particular, acquiring technical services, is not addressed. Lists of external experts exist, but experts are not audited by ASN to determine their capabilities prior to being included in the list. The outputs of experts' work are assessed based on a set of indicators. The 2009 IRRS mission reports recommended ASN audit IRSN's review and assessment functions against ASN's management system requirements. This recommendation has not been yet addressed.

The control of records is managed based on the relevant processes in the management system documentation and includes classification of records, retention time and location, as well as media to be used.

ASN uses various methods and communication channels, both internally and externally. In the area of public information, ASN provides information on its website. A note describes the various means of communication implemented in ASN and the associated methods of communication.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ASN relies to a significant extent on the technical support it receives from IRSN. All IRSN opinions are evaluated against criteria including timeliness, relevance, etc., but a systematic comprehensive audit of IRSN's support activities has not been performed.*	
(1)	**BASIS: GS-R-3 Para. 2.2 states that** *"The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement."*
(2)	**BASIS: GS-R-3 Para 5.23 states that** *"Suppliers of products shall be selected on the basis of specified criteria and their performance shall be evaluated."*
(3)	**BASIS: GS-R-3 Para 5.24 states that** *"Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the organization before the product is used."*
R6	**Recommendation: ASN should carry out a systematic and comprehensive audit of IRSN's review and assessment activities against ASN's MS requirements.**

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

ASN has a suite of performance indicators that is reviewed by management every quarter. The process described in the management system allows the indicators to be refined each year. The indicators are mainly quantitative measures of activity, e.g. numbers of inspections, numbers of letters issued, percentage of reports issued within defined timescales. They consequently measure ASN performance against ASN plans and as such do provide information on the effectiveness of ASN's management systems. They do not, however, indicate the regulatory effectiveness of ASN's activities on the safety performance of the licensees. Although ASN's regional offices review licensees' performance annually in the integrated safety assessment process (see Section 4.1), this is not linked to an evaluation of ASN's impact. Without indicators of ASN's effectiveness as a regulator, it will be difficult to establish a need for increased resource (see also Section 3.1).

ASN has several methods for measurement, assessment and improvement, including self-assessment, internal cross-audits, regular reviews of management system and a general annual review. These processes are conducted based on management system documents and include a number of performance indicators. The responsibility for internal audits is assigned to MEA. The results of the self-assessments, audits and other reviews are collected, recorded, analysed and monitored until resolution. The results of the general review are documented in the general review report. The improvement sheets are used to identify both non-conformances and suggestions for improvement.

ASN, as a French nuclear pressure equipment regulator, oversees manufacturers (design and manufacturing), notified bodies (independent conformity assessment) and licensees (operation and in-service inspection). ASN Nuclear Pressure Equipment Department (DEP) plays the role of a notified body for class I nuclear pressure equipment; the 2006 IRRS mission recommended that ASN demonstrate that they have the necessary qualifications and expertise to be accepted as a notified body. After the IRRS Follow-up in 2009, ASN decided to go through an ISO 17020 accreditation process focusing on inspection activities for DEP. Standard ISO 17020 (General criteria for the operation of various types of bodies performing inspections) sets requirements especially for quality, independence and competence. About 50 new documents (procedures, guides, organization charts, etc.) were created specific to DEP. Accreditation was finalized in July 1, 2013. Maintaining the accreditation includes audits two times per year.

4.6. SUMMARY

The ASN management system has evolved over time and the first version of ASN's integrated management system, documented in the management system manual, was issued in 2012. The ASN 12 key processes are divided into three categories: management, core and support processes. However, there were some observations concerning the comprehensiveness of the current management system. ASN should conduct a systematic analysis for identifying all the processes needed to deliver the regulatory mandate, taking into considerations all the relevant requirements. ASN should also audit IRSN's review and assessment functions against ASN's management system requirements. ASN Department of Nuclear Pressure Equipment Department received in 2013 an ISO 17020 accreditation focusing on inspection activities. About 50 new documents (procedures, guides, organization charts, etc.) were created specifically for DEP.

Safety culture is not currently addressed explicitly in ASN's management system. Changes should be made to relevant parts of the management system and associated processes should be developed and implemented to ensure that the management system promotes and supports a strong safety culture in the regulatory body.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The legislative framework for the licensing system for basic nuclear installations (BNIs) in France has been established under the provisions of the Code of environment, decree number 2007-1557 of 2 November 2007, the ministerial order of 7 February 2012 (BNI order), texts that govern all BNIs, the public health code and the labour code. The BNIs include:

a) Nuclear reactors
b) Installations meeting characteristics defined by a State Council decree for preparing, enriching, producing, processing or storing nuclear fuels or treating, storing or disposing of radioactive wastes;
c) Installations containing radioactive or fissile substances and meeting characteristics defined by a State Council decree;
d) Particle accelerators meeting characteristics defined by a State Council decree.

Any person intending to operate a BNI may, prior to initiating the authorisation procedure related to the creation stage, ask ASN for its opinion concerning all or some of the options it has chosen to ensure the safety of the planned BNI. In an "opinion", ASN specifies the extent to which the safety options presented by the applicant are such as to prevent or limit the risks, in light of the current technical and economic conditions. It may stipulate any additional studies and justifications necessary for a possible authorisation decree application. ASN may also set a validity period for its opinion. The applicant is notified of this opinion, which is forwarded to the ministers responsible for nuclear safety.

The authorization stages for BNIs include creation, commissioning, final shutdown, decommissioning and de-licensing, covering all stages i.e., siting, design, construction, commissioning, operation, decommissioning and removal from regulatory control. Major authorizations, such as for creation and decommissioning, are granted by the Government. ASN provides its opinion to the Government for these authorizations, whereas authorization for commissioning is issued by ASN. However, it has been observed that the Government has the legal right to make decisions that differ from the opinion of ASN, although there is no example so far. In addition, ASN defines the prescriptions relative to the design, construction and operation of the installation that it deems necessary as conditions for the authorizations. The IRRS team observed that the prescription for creation authorization is issued after the issuance of the authorization, with a gap of up to few months. Moreover, the prescriptions laying down the limits of discharges from the installation into the environment are subject to approval of the minister responsible for nuclear safety.

The applicant is required to submit a detailed demonstration of safety of the facility and the activity, commensurate with the potential magnitude and nature of the hazards, as part of the application for authorization. The Decree of 2 November 2007 establishes requirements for submission of information during various stages of authorization. Major documents submitted for creation authorization include details of licensee and site, environmental impact assessment, preliminary safety case, risk control study, decommissioning plan, technical capabilities of the organization, technical resources at its disposal, financial capabilities, etc. For a radioactive waste disposal installation, the decommissioning plan is replaced by a document presenting the envisaged procedures for final shutdown and subsequent supervision of it. During the commissioning authorization stage, the licensee submits a safety case comprising the updated preliminary safety case and the data, general operating rules the operator intends to implement, a study of the installation's waste management, an on-site emergency plan and an update of the

environmental impact assessment. The submission requirements for various authorization stages of all BNIs are the same; however, the level of detail varies for various types of installations.

The order of 7 February 2012 requires the licensee to schedule and implement appropriate random verifications of the measures taken in the application and periodic assessments of their suitability and effectiveness. These verifications and assessments are performed by persons other than those having carried out activities important for safety or its technical control. The persons conducting the verification and assessment, report directly to a person having authority over the technical control of the activity. The applications for licensing of BNIs undergo a thorough review and assessment process at ASN prior to issuance of the authorization.

The IRRS team observed that ASN has not yet issued a guidance document on the format and contents of the submissions that are required during various authorization stages, as required by GSR Part 1. The same observation was made during the previous IRRS mission to France and is amongst one of the open items of the follow-up mission conducted in 2009. The guidance document mentioned (especially related to the content of the (P)SAR) is included in the project formulated by ASN to complete the regulatory framework (la pyramide réglementaire). ASN is encouraged to put the necessary emphasis on completing the framework in a timely manner (see Chapter 9).

Major modifications to existing nuclear installations also require a prior authorization. These include the following:

a) Change of operator,
b) Changes in the perimeter/boundary,
c) Significant modification of the installation.

Under the Code of Environment, the licensees perform periodic safety reviews (PSR) every 10 years. ASN issues new license conditions as a result of a PSR. The licensee sends ASN and the minister responsible for nuclear safety a report including the conclusions of the review mentioned in the Code of Environment and, where applicable, the measures it envisages to remedy the observed anomalies or to improve the safety of its installation. After reviewing the report, ASN can impose new technical prescriptions. It sends its review of the report to the minister responsible for nuclear safety.

Prior to taking an authorization decision, ASN discusses the draft decision with the licensee. In case of disagreement with the draft decision, the licensee may appeal to the ASN commission. This process is described in a procedure that is under development. Once an authorization decision is issued, if the licensee has reservation on the decision, it may formally appeal to ASN in writing against the decision. A decision on the appeal may then be made; however, if the licensee still has reservations on the decision, it can challenge the decision in a court of law. The appeal process seems satisfactory; however, there is a need to document the process in written form.

ASN has conducted a thorough self-assessment based on the SARIS tool. The self-assessment highlighted the strengths in the authorization process and did not indicate any major weakness in the process.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

Electricity de France is the only licensee for nuclear power plants in France. Fifty-eight (58) nuclear power plant units have been commissioned in France, mostly in the 1980's. In recent history, only few licensing cases have been handled by ASN: Penly 3 (creation authorization in 2010-2011), Blayais 3 (introduction of MOX fuel and change in nuclear installation

administrative perimeter) and EPR Flamanville 3 (the application for commissioning and operating license may be submitted in 2015).

The siting and design aspects are reviewed by ASN, which provides its opinion to the Government in support to a decision regarding issuance of a creation authorization. The review follows the general rules relative to BNIs issued under the Order of 7 February 2012. ASN follows the technical guidelines for design and construction of the next generation of nuclear power plants with pressurized water reactors adopted during the French Groupe Permanent chargé des Réacteurs nucléaires (GPR)/German experts plenary meetings, held in October 2000 (adopted by ASN as a technical guide). These guidelines present the technical advice of GPR concerning the safety philosophy and approach as well as the general safety requirements to be applied for the design and construction of the next generation of nuclear power plants of the PWR (pressurized water reactor) type. ASN is in the process of developing a guide on the design of NPPs. Inputs for this guide include the technical guidelines, WENRA reference levels for existing reactors (2008), WENRA safety objective for new reactors (2010), WENRA report on the design of new NPPs (2013), post-Fukushima complementary safety assessment findings as well as IAEA Safety Requirements SSR-2/1. A guidance document on the general operating rules is planned to include the requirements of IAEA Safety Requirements SSR-2/2. With respect to NS-R-3, there exist requirements in the government Decree related to the hazards to be considered. Additionally, several guidance documents have been developed by ASN, such as those for flooding, seismicity (earthquake), meteorology and man-made hazards, as well as those for geological and geotechnical site analysis. ASN informed the IRRS team that, in France, no new sites for NPPs will be considered; possible new units may be built only on existing sites. Nevertheless, the siting aspects are evaluated during periodic safety reviews and the review of preliminary safety analysis report for a new NPP (such as was done for Flamanville 3 when the siting aspects were reviewed during the creation authorization stage).

A review of the ARM related to the modules on “Safety of NPP: Design” and “Safety of NPP: Commissioning and Operation” revealed that the requirements of SSR-2/1 and SSR-2/2 are covered in generic terms in higher-level documents. ASN intends to complete the guidance document to cover the requirements of SSR-2/1 and SSR-2/2 (also refer to chapter 9 for further details).

The ASN experts explained that various aspects of IAEA safety requirements are covered during the review of applications for various authorization stages.

The application for authorization of a nuclear power plant undergoes a thorough review and assessment process in which IRSN is involved to perform the technical review and supporting analysis. IRSN provides technical assistance to ASN under an agreement setting the basic framework for assistance. The review and assessment of authorization applications also verifies the technical competence of individuals having responsibilities for the safety of authorized facilities and activities. As mentioned earlier, PSR is not an authorization stage but the licensee submits its conclusions of PSR to ASN that also includes ageing as one of the major areas of the review.

The licensee is responsible for developing and implementing a training programme for personnel involved in activities important to safety. However, the legislative and regulatory framework in France does not require ASN to issue authorization to plant operating personnel.

5.3. AUTHORIZATION OF RESEARCH REACTORS

Eight research reactors are operating and two reactors are under construction, three reactors are in shutdown, two reactors are under decommissioning and one reactor is planned. In total, 16 research reactors are regulated by ASN currently.

Regarding code 20 of the Code of Conduct for the Safety of Research Reactors (hereinafter called CoC) and requirement 4.5 of the NS-R-4, the regulations and guidance should require the research reactor operating organization to put in place effective quality assurance programmes. This issue, which is related with the management system and quality assurance, is discussed in Chapter 9.3.

According to the CoC, the stages of extended shutdown and decommissioning are separate and divided. At the same time, Chapter IV of the Decree describes shutdown and decommissioning as one continuous process. As of 2014, two research reactors (Ulysse and Siloe) are under decommissioning, and three research reactors (Rapsodie, Phenix and Phebus) are in shutdown. To understand how ASN's regulatory activities have been conducted, inspection records of inspections conducted from 2009 to 2014 at of the Phenix research reactor were reviewed. The IRRS team concluded that ASN's regulatory activities were performed in accordance with the regulations and plans.

5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES

The fuel cycle in France comprises the front-end (conversion and enrichment of uranium, then fuel fabrication) and back-end (subsequent processing/recycling of spent fuel used in nuclear reactors). All of the main FCFs belong to AREVA.

As specified in Decree No. 2007-830 of 11 May 2007 relative to the BNI nomenclature, all nuclear facilities above a specific threshold set in the Decree are categorized as BNIs and are under the regulatory control of ASN. The authorization framework for FCFs (both front-end and back-end fuel cycle facilities) is the same as those for other BNIs.

The periodic safety review (PSR) applicable to all BNIs has also been applied to FCFs in France. License conditions on legacy waste management at La Hague plant is a good example of ASN's practice to issue new license conditions as a result of a PSR and its right to impose license conditions when it is deemed necessary.

However, concerning the management of legacy waste that is no more in compliance with current regulations, ASN can take enforcement actions (as for instance the shutdown of the BNI where this waste is stored) but ASN cannot use more precise gradation of sanctions (e.g. setting daily fines to the operator) to force the operator to carry out appropriate management steps for the safe management of this legacy waste (see chapter 8.1).

5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Radioactive Waste Management Facilities above the radioactivity threshold are regulated as BNIs and others are regulated by the ICPE regulations (Installations Classified on Environmental Protection Grounds). The authorization framework for radioactive waste predisposal management facilities is the same as those for other BNIs as specified in Decree 2007-1557.

Regarding radioactive waste disposal facilities, however, the authorization system for closure ("final closure" and "transition to the surveillance phase") of a disposal facility is clearly established in the Decree. Closure plan of a disposal facility is a part of the application file for creation authorization. This means that, for a radioactive waste disposal facility, the decommissioning plan that must be accompanied by an application for creation authorization of BNIs is replaced by a document presenting the envisaged procedures for final shutdown and subsequent supervision of it. This document comprises an initial analysis of the safety of the installation after final shutdown and transition to the surveillance phase. Stakeholders' involvement is an inherent part of the licensing process of the radioactive waste disposal facilities.

To close and go into the surveillance phase, the licensee must ask for a new authorization which is reviewed and given in the same procedure than for creation of final shutdown and decommissioning of BNI. The authorization (a decree) defines also the surveillance, supervision and maintenance measures to be done in the "surveillance phase". The installation is still a BNI regulated by ASN in this phase.

The French national agency for radioactive waste management (Andra) is the national operator for radioactive waste management, independent of the operators and waste producers. One the biggest challenges ASN may encounter is that the application file for the deep geological repository is to be submitted by Andra in a few years. However ASN has not yet established a dedicated team to handle the significant effort that will be generated by this authorization project.

More specifically for the disposal of LL-LL waste, Andra will propose disposal options in 2015. If the sub-surface disposal option is proposed by Andra, ASN should develop in the framework of the authorization process safety guides for that type of disposal facility (see Section 9.5).

Therefore, ASN and IRSN should increase the capacity of the dedicated staff to prepare the assessments of the deep geological disposal application file and, depending on the chosen option, of the sub-surface LL-LL disposal application file as already identified by ASN (see Section 3.3 and ASN action number 6.7 and 6.8).

5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES

The authorization of radiation sources and facilities by ASN is undertaken mainly by the Regional Divisions. The Transport and Sources Department (DTS) at ASN headquarters is responsible for authorization of the suppliers of radiation sources (including medical suppliers). However, this is only for radioactive sources and is not yet implemented for radiation generators. This is currently being drafted for non-medical radiation generators by ASN. There are different categories of authorisation such as supply, import, export, possess, use and manufacture.

Authorization of medical and non-medical uses of ionising radiation is undertaken by the Regional Divisions of ASN. The Transport and Source Department (DTS) and the Ionising Radiation and Health Department (DIS) at ASN headquarters produce the guidance for assessment of authorisations.

ASN ensures proper radiation protection and safety of medical exposure through authorization or notification of all medical practices, with no exemptions. ASN has published a decision that identifies the devices that are required to be notified for medical, medico-legal, biomedical research and veterinary purposes. This list also includes interventional radiology devices. Medical authorizations are normally issued to a person and not to an organization, placing the full responsibility on the authorized person to comply with all the relevant requirements in the regulations. However, this person is not usually in a position to fulfil all these responsibilities. Radiotherapy, nuclear medicine and CT require to be authorized, while all other medical practices are submitted for notification only. ASN has categorized interventional radiology in the same risk-category as radiotherapy and therapeutic nuclear medicine. Interventional radiology should therefore be subject to authorization for consistent application of the graded approach. Reporting of incidents of deterministic effects on patients who have undergone interventional radiological procedures strongly supports this suggestion. This issue was also addressed in the IRRS mission in 2006 and is included in the ASN Action Plan from the IRRS mission.

The Public Health Code (PHC) requires the applicant to submit documentation to support the demonstration of safety of the activity, and ASN has developed application forms, which are available on its website. The forms available are for different activities e.g., use of sealed sources, particle accelerators, x-ray generators etc. and cover different stages in the life cycle of

the facility e.g., new authorisation, modification, renewal. The authorization period is limited to a maximum of 10 years, and most authorizations granted by ASN are for a period of five years. ASN should adopt an authorization renewal period that takes account of the hazard of the sources or devices, inspection frequency, and operating feedback.

Although ASN has many thousands of authorizations, it does not appear to have a documented plan that indicates when authorizations are due for renewal.

Although ASN has specific authorization forms relevant for different source and facility types e.g., sealed sources, unsealed sources, particle accelerators, x-ray generators etc., these are not categorized according to the IAEA standards, GSR Part 3, para 3.56. However, ASN does have a categorization of its sealed sources into High Activity Sources and non-High Activity Sources, where the High Activity Sources are approximately equivalent to Category 1, 2 and 3 sources as defined in Schedule II of GSR Part 3. ASN should develop a categorisation scheme for radiation sources for licensees fully in accordance with the IAEA Standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team noted that the principle of graded approach is not consistently applied in all aspects related to the authorization of radiation sources:* - *Interventional radiology only requires notification even though ASN has identified this practice with a risk of delivering high doses to both the patient and staff.* - *The period of authorization does not seem to be commensurate with the radiation risks associated with facilities and activities.* - *Categorization of radioactive sources by the licensee does not appear to be formally established as a requirement by the regulator in accordance with the IAEA standards.*	
(1)	**BASIS: GSR Part 3, Para 2.31 states that** *"The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation"*
(2)	**BASIS: GSR Part 3 Para 3.8 states that "***Any person or organization intending to carry out any of the actions specified in para. 3.5 shall, unless notification alone is sufficient, apply to the regulatory body for authorization, which shall take the form of either registration or licensing."*
(3)	**BASIS: GSR Part 3, Para 3.56 states that** *"Registrants and licensees shall ensure that sealed sources are categorized in accordance with the categorization scheme set out in Schedule II, and in accordance with the requirements of the regulatory body."*
R7	**Recommendation: The regulatory body should ensure a more consistent implementation of the graded approach for the authorization of radiation sources and facilities.**

According to R.1333-24, the application for authorization or renewal thereof is submitted by the natural person or the representative of the legal entity who will be responsible for the proposed nuclear activity and countersigned by the head of the establishment if there is one. It appears that this is the case for some practices such as medical practices, where the authorization is given to the medical practitioner, and in industrial practices (NDT), where the authorization is given to

the physical person in charge of the nuclear activity, knowing that the person authorized is the employee. In this case, it seems that the first responsibility is diluted between the holder of authorization and the head of the organization.

However, in 2011, this process was initiated particularly in the industrial practices, but is not yet fully implemented.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Authorizations for some practices in the medical and industrial radiography (NDT) fields are issued to the medical practitioner and the physical person in charge of the nuclear activity respectively, instead of the legal entity.*	
(1)	**BASIS: GSR Part 3, Para. 3.13 states that** *"Registrants and licensees shall bear the responsibility for setting up and implementing the technical and organizational measures that are necessary for protection and safety for the practices and sources for which they are authorized. Registrants and licensees may designate suitably qualified persons to carry out tasks relating to these responsibilities, but they shall retain the prime responsibility for protection and safety. Registrants and licensees shall document the names and responsibilities of persons"*
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.**

The users or suppliers must notify the sources authorized by ASN to IRSN as required by regulations. This applies also for import or export of radioactive sources. In addition, ASN notifies IRSN of all its authorizations related to radioactive sources. Hence, although IRSN is not involved in the granting of an authorization for radioactive sources, it is responsible for the registration of all sources that are authorised, this being a requirement by regulation. The maintenance and development of the IRSN national sealed source register was discussed amongst the IRRS team and counterparts. It was concluded that the level of input from ASN into the development and maintenance of this database by IRSN does not appear to be adequate. It was noted that there is a lack of detailed regulation regarding the process of movement registration, but that a draft ASN decision is being prepared to resolve this.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The maintenance and development of the national sealed source register is undertaken by IRSN, but ASN does not appear to have sufficient input into this process to assist in the regulatory control of sealed sources*	
(1)	**BASIS: GSR Part 1, Requirement 35 states that** *"The regulatory body shall make provision for establishing and maintaining and retrieving adequate records relating to the safety of facilities and activities."*
R8	**Recommendation: The Government should clearly define in the regulatory framework the responsibilities of ASN with regard to the national sealed sources register.**

In addition to the national sealed source register, IRSN is also responsible for maintaining the register of occupational exposures. However, ASN does not have the ability at this time to access the occupational exposure database directly (see Recommendation in Chapter 11).

5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Final shutdown and decommissioning of a basic nuclear installation are subject to prior authorization.

The content of the authorization application file comprises (according to the Decree 2007-1557) the provisions concerning the shutdown conditions, the decommissioning and waste management procedures, and also concerning the surveillance and subsequent maintenance of the installation site. Considering current scientific and technical knowledge at the time and the projected future use of the site, a demonstration must be provided that the risks or drawbacks for the major interests, namely public health, the protection of nature and environment are prevented or sufficiently limited.

The authorization sets forth the decommissioning characteristics, the decommissioning time frame and the types of operations under the licensee's responsibility after decommissioning. To implement the authorization, ASN defines the prescriptions relative to decommissioning necessary to protect the major interests.

However, the regulatory texts do not prescribe the type of records and information to be kept during the lifetime of a BNI. The IRRS team suggests specifying, in a resolution, which records and information are to be kept during the lifetime of the BNI in view of its future decommissioning, as also raised by ASN in its action plan (action 5.2).

Article 40 of the Decree 2007-1557 of 2 November 2007 describes the format and content of the application file for de-licensing, together with the consultation process. ASN forwards the de-licensing file to the Prefect with a memorandum explaining the effect of a de-licensing measure. The Prefect obtains the opinions of the communes concerned. ASN then sends the application file, along with the explanatory notice, to the local information committee. ASN then submits a resolution for installation de-licensing to the minister responsible for nuclear safety for approval.

ASN may enact a de-licensing decision dependent on the introduction of the public protection restrictions mentioned in L.593-5 of the Environment Code, which guarantee that the underlying land and the vicinity of the installation will be managed in a way appropriate to the risks remaining after its decommissioning, in particular with regard to the future use of the site.

The following aspects are also covered by the French regulation (Decree 2007-1557): preservation of key staff, responsibilities for financial provisions and demonstration of compliance with the decommissioning plan. In the case of a site that cannot be released for unrestricted use, the prefect controls the site.

Given the unprecedented safety challenges ASN and IRSN will be facing, starting in 2015 with the decommissioning activities of the basic nuclear installations, ASN and IRSN should increase the capacity of the dedicated staff. The IRRS team is therefore supporting strengthening the human and financial resources allocated to ASN and IRSN as already identified by ASN (see section 3.3 and ASN action number 6.9).

5.8. AUTHORIZATION OF TRANSPORT ACTIVITIES

The requirements of TS-R-1, Regulations for the Safe Transport of Radioactive Material, paragraph 802, state that the Competent Authority approval shall be required for special form of radioactive material, low dispersible radioactive material, packages containing 0.1 kg or more of

uranium hexafluoride, packages containing fissile material unless excepted, Type B(U) packages, Type B(M) packages, Type C packages, special arrangements, certain shipments, radiation protection programmes for special use vessels and the calculation of radionuclide values that are not listed in Table 2 to TS-R-1. By Order, it is specified that ASN is the Competent Authority for the carriage of radioactive or fissile materials intended for civilian purposes. ASN identified that there are some types of authorization that are not in use in France and therefore have not been reviewed or authorized, specifically for low dispersible material or for civilian use of a Type C package. ASN is prepared to review these if an application is received. Authorizations for Type B and fissile packages, as well as special arrangements, are routinely issued and include the requirements of paragraphs 827 through 829 of TS-R-1. ASN has implemented provisions for Type B and fissile packaging that are more restrictive than TS-R-1, paragraphs 816 and 817, to phase out certificates of approval for package designs approved under the 1973 and 1985 editions of the IAEA Regulations for the Safe Transport for Radioactive Material. ASN has identified in the advanced review material the need to encourage applicants to develop new packages to replace those older designs. This is captured as Action Item 5.4 in the Self-Assessment Action Plan.

5.9. SUMMARY

ASN, being the nuclear regulatory authority in France, issues authorizations to BNIs, radiation sources and facilities, and transportation of fissile and radioactive materials. The authorization stages for BNIs include creation, commissioning, final shutdown and decommissioning (or final closure and transition to the surveillance phase for waste disposal facility) and de-licensing. The authorizations for creation, final shutdown, decommissioning and de-licensing are issued by the Government, whereas authorization for commissioning is issued by ASN. ASN also issued requisites (conditions to be met by the licensee) during all authorization stages. The licensees of BNIs are required to undergo a periodic safety review, even though this is not an authorization stage.

The facilities involving radioactive sources and radiation generators require authorization and notification; however, these can be exempted depending on their characteristics, use and potential exposure that these can cause. Authorizations for transport are in line with all requirements of the IAEA Regulations for Safe Transport of Radioactive Material, TS-R-1, and are routinely issued.

ASN has a well-defined authorization system covering the entire life cycle of facilities and activities. The authorization system is, in general, in line with IAEA safety standards whereas additional steps have been planned or are in the pipeline for further improvement. ASN has performed a thorough self-assessment based on IAEA's SARIS tool, providing the details on how they comply with IAEA safety standards, identifying areas for further improvement, and have drafted a detailed plan for the corrective actions for improvement.

The team has also identified certain areas for improvement in the authorization process (details are provided in sections 5.1 to 5.8 above) including implementation of a graded approach in the authorization of radiation sources and facilities, issuance of the authorization for radiation sources and facilities to the appropriate legal entity, and responsibilities of ASN with regard to the national sealed source database.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

As one of the necessary functions of the regulatory body, review and assessment is carried out during the authorization process and for plant modifications. Further safety reviews are linked to PSRs and the operating experience feedback process. The depth of the review and assessment performed depends on the safety significance of the issues treated and follows the application of the graded approach principle, as stated in the 2012 Order, namely that the overall approach has to be commensurate with the extent of the risks or drawbacks inherent to the installation, and to take into consideration all relevant technical, organisational and human aspects. Within this principle, all radiation risks are assessed.

A transparent process is established, which assures traceability of ASN opinions, with detailed justification (fiche de mise à la signature) of accepted or rejected third-party comments and advices.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

For NPPs, review and assessment activities are performed under the lead of ASN, who has the responsibility of drawing the final conclusions. Nonetheless, for review and assessment, ASN relies on the support of TSOs and authorised bodies with the necessary in-depth expert knowledge on specific topics. Before issuing the final ASN opinion, be it an official decision within an authorisation process or, for example, an enforcement letter for actions to be taken in the light of an operating experience feedback, the advisory committees of experts can be requested to provide further advice. Also, a public consultation on the draft decision may take place.

The type and number of documents to be submitted for review and assessment depend on the type of application, and are described in the regulatory framework in various levels of detail. Completion of the regulatory framework is pursued by ASN through an established project for issuing additional guidance documents (see Chapter 9).

As an application of the graded approach, NPP modifications are treated according to their safety relevance. First, there are those significant modifications that require a change of the creation authorization decree (criteria for which are defined in Art. 31 of the Decree 2007-1557). Beyond those, modifications are classified according to the criteria of Art. 26 of the Decree 2007-1557).

Modifications pursuant to Art. 26 may be divided in three sub-classes:

- Modifications that require a change of ASN conditions attached to an authorization which entail the whole formal process of issuing an ASN decision signed by the ASN commission (including public consultation);
- Modifications that do not fall under sub-class 1) for which a consent letter is produced by ASN signed by a department head or deputy DG;
- Minor modifications, which are approved uniquely by a licensee internal independent review process.

For modifications falling in sub-class 3), the applicable criteria are further specified in Decree 2007-1557. ASN has to approve both the licensee's internal independent review process and the type of modifications that can be treated as minor modifications (in this respect, an ASN decision has been recently issued to the NPP licensee defining the agreed types of modifications). With regard to sub-class 2) modifications, according to the legal rules, there is a maximum delay (amounting to 1 year in total) within which ASN has to provide its formal opinion or either the application is to be considered accepted. However, as part of a bilateral agreement, it is

understood that the NPP licensee will not perform the modification unless ASN consent is formally provided.

For activities related to operating experience feedback, ASN has established an articulated process to ensure that the review of each event is performed, that the measures taken or planned by the licensee are checked and that the generic lessons from the event are taken into consideration. The main actors of this process are the regional divisions, the ASN headquarters and the IRSN. Periodic meetings are organized with the licensee on the specific topic of operating experience, in which both national and international events are discussed. The review and assessment of events is tracked in a dedicated IT system of ASN. In case of major national safety relevant events, reactive inspections can be performed by the regional divisions. Beyond that, IRSN supports ASN also with a global review of lessons learned through operating experience feedback, producing a detailed report in a three years cycle, which is then submitted to the GPR for further advice. As a result, issues can be taken up for immediate enforcement or referred to the PSR process (10 year cycle).

Periodic safety reviews are required for all BNIs at the latest every ten years as prescribed in the Code of Environment. The objectives of PSRs include checking the conformity of the NPP with its licensing basis and assessing the need for improvements, taking into account the operating experience as well as the evolution of knowledge and of the rules applying to similar installations (also internationally). Topics covered by the PSR include: re-evaluation of external hazards, PSA, severe accident management and, after 30 years of operation, ageing management. Additional topics to be investigated can originate from generic lessons learned from operating experience (in the case of the 3rd PSR for the 1300 MWe series, e.g., dilution accidents, long-lasting station blackouts, external flooding). The process of conducting a PSR in France is divided in a generic and a plant specific part. The generic part is made at the level of plant groups (e.g., all 1300 MWe units) and is supported by several in-depth analyses by IRSN as well as by technical advice from the GPR. At the end of the generic part, ASN issues an opinion with a series of recommendations to the licensee. The plant specific part is conducted after the long PSR outage of each unit. After this outage, the licensee submits an additional report explaining how the recommendations and measures requested in the generic PSR evaluation by ASN have been implemented and what is still to be done. A review of the plant specific report is performed by the ASN regional divisions, the result of which is an ASN resolution, possibly setting further requirements for the continued operation of the unit.

With regard to an integrated safety assessment of NPPs, there is an effort by ASN to produce a so-called “monography” per site, which in turn leads to ASN concluding formally in its official yearly report on whether the NPPs under its oversight were safe and how they performed compared to previous years. The work is performed in strict collaboration between the regional divisions and ASN headquarters, and is based on a standard template fixing the elements of evaluations (e.g., safety significant events, results of inspections). It should be recognised, however, that the assessment is qualitative in nature. In order to improve consistency of evaluations across all sites, ASN holds workshops with the regional divisions, which should foster a common understanding of the tool and its intended goals.

6.2.1. MANAGEMENT OF REVIEW AND ASSESSMENT

For review and assessment, there is no dedicated ASN internal guidance, but different input is found in those processes where these activities are taking places, i.e. authorisation (including Art. 26 modifications) and operating experience feedback. Beyond that, the regulatory body is organised in such a way that experienced people are tasked with leading the review and assessment of the most important issues, while new collaborators learn on the job. In view of the

naturally high fluctuation rate of ASN staff, the challenge is to have careful succession planning that allows an effective knowledge transfer from experienced staff to newcomers (see also the corresponding discussions in Chapter 1 and 3). At the same time, more extensive and detailed guidance documents would help knowledge management under the conditions mentioned.

In relation to PSR, ASN has a well-established praxis that results in a periodic safety review programme spanning over several years, addressing issues in a top-down approach from generic to unit specific (see previous section). However, ASN internal instructions and process description for PSR activities are missing. A new draft procedure to be included in the management system is available, as well as a more detailed guidance document fixing the main recurrent topics of a PSR and other aspects related to the project of PSR review and assessment.

The scope of PSRs that have been performed or are currently being performed in France is not fully consistent with all the safety factors indicated in SSG-25. In some areas the effort produced is broader, considering that some topics are reviewed with a higher frequency (e.g. operating experience feedback in a 3-year cycle) and fed back into the PSR process, if need be. Other safety factors are treated separately and not included in PSRs, such as organization, the management system, safety culture and emergency preparedness.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *For PSR activities, internal instructions and process description are missing, though a draft is available. In the draft not all the safety factors of SSG-25 are addressed.*	
(1)	**BASIS: GSR Part 1 Para 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body."*
(2)	**BASIS: SSR-2/2 Para 4.44 states that** *"Safety reviews shall address, in an appropriate manner, the consequences of the cumulative effects of plant ageing and plant modification, equipment requalification, operating experience, current standards, technical developments, and organizational and management issues, as well as siting aspects. Safety reviews shall be aimed at ensuring a high level of safety throughout the operating lifetime of the plant"*
(3)	**BASIS: SSG-25 Para 2.12 states that** *"A PSR should provide a comprehensive assessment of the safety of the nuclear power plant. Since the complex process of conducting a PSR can be aided by appropriate subdivision of tasks, this Safety Guide sets out these tasks in accordance with 14 safety factors. These safety factors have been selected on the basis of international experience and are intended to cover all aspects important to the safety of an operating nuclear power plant. This subdivision is, however, not unique. In cases where the number of safety factors used and/or their grouping is different (for example, to meet the specific needs of the operating organization or regulatory body or owing to particular aspects of the nuclear power plant under review), the comprehensiveness of the PSR should be ensured by other means."*
S8	**Suggestion: The regulatory body should consider issuing internal guidance on the review and assessment activities to be undertaken in the frame of the**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	periodic safety reviews covering all safety factors of SSG-25.

Review and assessment activities typically end with an ASN decision or letter informing the applicant of regulatory results and conclusions. There are several steps leading to an ASN decision, for example in the frame of the authorization process. For such important issues, requiring extensive resources and an important work load deployed over several years, a strategy note is issued after approval by the ASN commission detailing the scope of the review to be performed, the main steps of the review, the risks associated with the project and the time schedule. A table of content of the safety evaluation report to be produced as basis for the official decision is also included.

The main actors for the review and assessment of NPPs, performed under the lead of ASN, are the TSO(s), mainly IRSN, and the advisory committee of experts for NPPs (GPR).

Traceability of the regulatory decisions is guaranteed by means of a sort of log file (fiche de mise à la signature) that is attached internally to each decision. The log file contains entries detailing on one hand the quality control process and on the other hand the justifications leading to the acceptance or rejection of the technical recommendations by the TSO and by the advisory committee. The same applies to the comments by the licensee and the public.

6.2.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The central departments of ASN are managing the activities related to review and assessment and are organised in such a manner as to ensure that the necessary competence is available in-house. As a minimum requirement, the ASN specialists are able to grasp the safety significance of the issues they deal with and to understand the conclusions of the in-depth analysis possibly provided by the TSO(s). On all major issues, IRSN provides the experts for the in-depth review and assessment, except non-radiological environmental impact assessments, for which review and assessment is performed by ASN experts.

Once an application is submitted by the licensee, there is a first cursory review phase, during which it is also decided whether the safety relevance of the issue warrants an in-depth review by IRSN. If this is the case, a clear definition of the scope of the required review, the main questions to be answered and the time schedule for the delivery of results are agreed and set down officially in an ASN request for support by IRSN. Beyond IRSN, there is a pool of expert companies, each associated with different fields of expertise, from which ASN can draw additional support for review and assessment, for example in the case of lack of manpower from IRSN.

In order to improve the framework related to the review and assessment performed by the main TSO (IRSN), ASN is in the process of agreeing and establishing a classification of the type of analysis IRSN is doing for them. In a perspective of a graded approach, a distinction is hence made among those assessments IRSN performs on simple or recurrent subjects, and the detailed in-depth analyses needed in preparation for a GPR meeting.

The planning of the review and assessment work, which is submitted for GPR advice, is based on a multi-year strategic planning of topics, which is discussed and adjusted on the basis of the regular meetings held among ASN, IRSN and the president of the GPR.

For transient analyses IRSN has at its disposal all the state-of-the-art codes necessary to check the claims by the licensee as found in the application files. IRSN also has PSA levels 1 and 2

codes at its disposal. Because of their involvement in research activities, IRSN has in general access to most updated results. Other codes to check the applicant calculations in the field of nuclear pressure equipment are available from the notified bodies approved by ASN.

6.2.3. BASES FOR REVIEW AND ASSESSMENT

The French regulatory framework specifies the requirements that form the basis for review and assessment activities. Higher-level requirements are set in the law and orders (especially the Code of Environment, Order of 7 February 2012). On a lower level but still legally binding, there are a series of associated ASN regulatory decisions. Below those, there are the ASN guidelines, which constitute a non-legally binding basis.

There is a set of acceptance criteria defined in the regulations, though ASN acknowledges that it is still working towards establishing a comprehensive and structured system. Currently, the "Technical Guidelines" (technical guidelines for design and construction of the next generation of nuclear power plants with pressurized water reactors, adopted during the GPR/German experts plenary meetings held in October 2000) provide guidance on deterministic and probabilistic safety analysis rules for Design Basis Accidents (DBA) and acceptance criteria; these rules are conservative for design basis accidents and refer to the use of "decoupling" acceptance criteria (meaning not directly linked with radiological protection limit). Concerning radiation protection targets, the technical guidelines establish a qualitative objective, which for DBA is, "no necessity of protective measures for people living in the vicinity of the damaged plant (no evacuation, no sheltering)". The regulations set some "reference value" for protective measure to the population. These references values are the following:

- sheltering if the predicted effective dose exceeds 10 mSv;
- evacuation if the predicted effective dose exceeds 50 mSv;
- administration of stable iodine, when the predicted thyroid dose exceeds 50 mSv.

The technical guidelines also set some probabilistic safety goals for NPPs. Beyond that, the development and use of probabilistic safety analyses is regulated in an ASN guideline.

In relation to the design of NPPs, a draft guideline is being processed which should cover all IAEA Safety Requirements contained in SSR-2/1.

Several guidelines set the requirements related to external hazards. The guideline on flooding hazards has been recently updated (2013). Other guidelines are in the pipeline for updating. In fact, ASN has established the need to update and complete its regulatory framework by means of decisions (legally binding) or guidelines (non legally binding) so that it gets full in line with the IAEA Standards. A project has been set up grouping the topics that need to be covered. Some 15 regulations are at various stages of development (see Chapter 9).

6.2.4. PERFORMANCE OF THE REVIEW AND ASSESSMENT

As a file is submitted to ASN for review and assessment, a cursory review is performed as a first step in order to establish whether the submitted file is complete and with the necessary level of details. Request for additional information can be sent to the applicant at this stage. Secondly it is decided whether a detailed analysis by IRSN is needed. ASN puts emphasis on the independence of IRSN expert advice and, although it is informed of all requests for additional information and technical meetings between IRSN and the licensee, does not necessarily participate in the technical exchanges and rather allows direct contact between its TSO and the licensee.

IRSN is consulted for all major safety topics and performs in-depth review in case of authorization applications, PSRs, generic issues related to safety significant events in France and abroad, and plant modifications.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

To apply for the creation for a research reactor on the ground of the Decree 2007-1557, the applicant should submit documents of environmental impact assessment, a preliminary safety case, a risk control study, decommissioning plan, etc. Article 10 of the Decree provides requirements for the preliminary safety case, and the requirements are similar to those for the safety analysis report, which are stated in NS-R-4.

According to NS-R-4 requirement 3.6, a SAR shall give a detailed description of the reactor site, the reactor, experimental devices and all other facilities and activities with safety significance. However, the contents of the safety case do not include all the elements contained in NS-R-4 requirements. ASN recognized in 2006 the need for a guideline to provide the subjects and criteria to be included and how to develop the report. However, this guideline has not yet been developed. Within the project ASN established for completing the regulatory framework, a guideline on the content of SAR is foreseen (see Recommendation in Chapter 9). The specific characteristics and features of research reactors should be considered with particular care in the planned guideline.

Sixteen research reactors are operating, in shutdown, or under constructing in France. Even though the respective reactors have different features, purpose and operating lifetime, periodic safety review (PSR) has been carried out for all available reactors systematically.

6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

Review and assessment activities at the various stages of the FCFs are the same as those for other BNIs, including the performance of PSRs.

Codes and standards that can be used by FCFs operators are presented in various ASN guides. However, the operators should select the codes and standards to be used and justify the applicability by themselves since ASN's position on the use of codes and standards is not very explicit. Regarding this issue, the IRRS team supports ASN's action plan to formalize further its position on the use of codes, standards and related criteria by operators, which may also improve the level of consistency in the review and assessment (see ASN action number 6.2).

In accordance with the provisions, review and assessment on physical protection is duly conducted by the Department of energy, technically supported by IRSN.

6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Concerning the disposal facilities, the regulatory body requires that the safety case and its supporting safety assessments be documented to a level of detail and quality sufficient to inform and support the decision to be made at each step, and to allow for their independent review. The regulatory body requires the operator to prepare and update a safety case and supporting safety assessment, as necessary, at each step in the development, operation and closure of a disposal facility, in compliance with legal and regulatory requirements, and to submit it to the regulatory body for approval.

The order of 7 February 2012 requires that, according to the principle of defence in depth, the licensee must have a cautious design approach, integrating design margins and, wherever necessary, introducing adequate redundancy, diversification and physical separation of the elements important for protection that fulfil functions necessary for the demonstration of nuclear safety, to obtain a high level of reliability and to guarantee the functions mentioned in the preceding paragraph. Furthermore, specifically for the disposal of long-lived waste, the basic safety rules establish that the determination and taking into account of uncertainties are essential elements of the safety analysis. The safety demonstration must clearly identify how the on-site

investigations, research program results, design provisions, hypotheses made for the evaluation and the sensitivity studies have allowed the appreciation of the uncertainties and taken them into account. The residual uncertainty must be evaluated, according to their type, in a qualitative or quantitative way. Expert opinion may be used; the traceability of these opinions must be established. The evaluation of component performance, behaviour of the entire disposal system and individual exposures must be accompanied by pertinent elements demonstrating the conservative nature of the results obtained, as well as the proper basis for design choices. In addition, sensitivity studies must be carried out to identify the most important parameters and to justify the simplifying assumptions made. The sensitivity analyses are used to identify the areas where more analysis efforts are needed (situations taken into account), to understand and rank the processes used (models) or characterized (parameters) and to increase the credibility of the evaluation results.

Cigéo-project

Following the iterations in 1998, 2001 and 2005, based mainly on the long-term safety of the repository, Andra presented in 2009 safety, reversibility and design options. They were examined in 2010 by ASN and its technical support organization, IRSN, notably identifying the main points requiring further information for the licensing submission.

6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES

ASN performs a review and assessment of information prior to authorization, following modifications and when authorizations are due for renewal. Sample checks are also performed during inspections. Normally, authorizations are renewed after a five-year period (see section 5.6). The results of the review and assessments are documented in ASN reports that provide details of what has been assessed and whether regulatory requirements have been met. The conduct of reviews and assessment for authorizations is governed by the ASN internal procedure established in the notice SMQ/DIT/QPR/AUT/ASN/000100/2009.

Although it appears that the level of review and assessment required is undertaken in a graded approach commensurate with the risk of the activity, ASN does not appear to have documented the process. ASN should consider formally documenting the process on how assessment of facilities is graded on a safety basis (please refer to the Suggestion in section 9).

6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

On the basis of the Order of 7th February 2012 and the Environment Code, periodic safety reviews are carried out during the life of the BNI's (including also the decommissioning of the installation).

During the decommissioning of the BNI's, the decommissioning plan and its related safety assessments is updated by the licensee and reviewed by ASN.

The training programme for individuals responsible for reviewing decommissioning activities includes health, safety and environmental matters.

For new facilities, consideration of decommissioning begins early in the design stage and continues through to the termination of the practice or the final release of the facility from regulatory control. The consideration of decommissioning is therefore included in the review and assessment process.

6.8. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

ASN's primary role for transport review and assessment is for authorization of packaging in accordance with TS-R-1. ASN can issue approvals for radioactive material in special form and low dispersible radioactive materials; packages containing 0.1 kg or more of uranium hexafluoride; packages containing fissile material; Type B and Type C packaging designs. The assessment process is described in ASN Guide No. 7, "Transport of Packages or Radioactive Materials for Civil Use on Public Roads." For a new transport package design, ASN has three main stages for their review process leading up to the issuance of a certificate of approval: the preliminary safety report; the test programme; and the design safety report. After each of these stages, ASN issues a letter stating the points that have been accepted, rejected or need completing. As described in the ASN-IRSN Framework Document, IRSN provides technical support to ASN for transport approvals, including all of the types listed above. ASN may also request an assessment by the advisory committee for transport before making a final conclusion regarding the acceptability of a transport application. Taking into consideration the IRSN assessment and advisory committee response, ASN issues the approvals.

Approval certificates are typically issued for a five-year period. As older packages are reviewed for renewal of the certificate, ASN evaluates the design against current regulatory requirements and incorporate enhanced assessment methods or any lesson learned during use of the package. An example is the review and assessment of the model TN-13/2. ASN required the applicant to consider a new drop orientation, which resulted in a revised cover design. ASN issued an interim approval to allow limited shipments with appropriate compensatory measure and a full renewal of the certificate for the design with the new cover plate. This example illustrates ASN's focus on continuous improvement and on ensuring compliance with the requirements of TS-R-1.

ASN reviews and approves the training organization and programme for certification of Class 7 drivers. Applications for approval of drop test targets (locations where the facility meets the requirements of TS-R-1, paragraph 717) are reviewed and ASN has issued letters for four test facilities that satisfactorily meet regulatory requirements. Currently, ASN provides review and assessment for implementation of radiation protection programmes for the transport through inspection. As noted in Section 9.8, ASN's authority to require notification from carriers of radioactive material is needed to enhance the review and approval of radiation protection programmes for transport.

6.9. SUMMARY

Review and assessment for BNIs is performed by ASN mainly within the frame of authorisation, plant modification, operating experience feedback and periodic safety reviews. The type of documents subject to review and assessment is very diverse in scope and content and the regulatory body applies a graded approach. ASN is supported by its main TSO, IRSN, with in-depth analyses on the major safety relevant issues. A second technical advice is the one provided by the various Advisory Committees of Experts (GPE).

The review and assessment process for evaluating the suitability of radiation source facilities has been examined and found to be essentially adequate, although the review team proposes a stricter documentation on how the assessment of such facilities is graded on a safety basis. A corresponding suggestion, to clarify the graded approach used in the regulations and guides for different facilities and activities, may be found in section 9.

With regard to the safety assessment performed for transport activities, the team concludes that it is fully consistent with the relevant IAEA requirements.

The team has also identified an area for improvement with regard to regulatory guidance for the applicants and licensees of BNIs, for example with respect to the content of a safety analysis report. ASN has initiated a project defining the scope and schedule for completing the regulatory framework. A corresponding recommendation from the review team, encouraging timely implementation of the ASN plan, may be found in section 9.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION APPROACHES, METHODS AND PLANS

ASN carries out inspections to verify that licensees comply with legislation and conditions specified in authorizations. The verifications are carried out in the form of inspections by ASN inspectors whose rights and duties are determined by the Environment Code, the Labour Code and the Public Health Code. During the inspections, ASN inspectors verify compliance of licensees with requirements contained in the relevant Acts, implementing regulations and conditions specified in licenses.

The monitoring and assessment of nuclear safety and radiation protection in all nuclear installations and workplaces with ionizing radiation sources is one of ASN permanent priorities. ASN fulfils this obligation through its planned annual inspection program.

All common methods mentioned in IAEA GS-G-1.3 are utilized: these include monitoring, direct observation, discussions, reviews, and examinations of procedures, records and documentation. Independent sampling, tests and measurements are mainly conducted in the area of radiation protection, effluent discharges and radioactive waste.

ASN has implemented a systematic inspection planning and evaluation program covering the construction, operation and decommissioning stages of BNIs.

Overall program guidance is provided through several internal documents, detailed inspection guidance is given in various inspection procedures. Inspections performed by ASN are conducted in accordance with inspection plan, which is prepared on an annual basis. If trends in any of the inspected areas indicate increased risk, for instance following relevant events, then in depth or more frequent inspections are planned and performed. The inspection plans are published in the form of MS Excel tables published on ASN intranet. Plans describe all items needed for effective management of inspections.

The inspection frequency depends, besides of baseline frequency defined in ASN procedures, upon:

- the level of the impact on nuclear safety and radiation protection,
- any needs that may arise from operational experience feedback,
- an evaluation of the inspection of the specific area in the previous period and,
- the fulfilment of obligatory conditions and requirements of the ASN.

ASN publishes the main results of its inspection activities continuously on its website and on an annual basis in the annual report.

7.1.2. INSPECTION PROCESSES AND PRACTICES

ASN has a formal inspection program in place to ensure that licensees comply with legislation, regulations, other regulatory requirements and the terms of their specific licenses (ASN resolutions). The inspection program is described in numerous ASN documents and guidance procedures in accordance with ASN legislative authority under the relevant acts. The inspection program covers all nuclear installations including NPPs, research reactors, waste treatment facilities, fuel cycle facilities, laboratories, pressure equipment manufacturers, contractors, as well as transport and users of ionizing radiation.

ASN implements a graded approach in the conduct of its inspection program, applying its inspection resources in a manner that is consistent with the safety significance of the regulated activity as well as the potential hazard to the public health and safety, or the environment.

ASN is supported by IRSN to accomplish its inspection programme. Cooperation with IRSN is based on a long term bilateral agreement which defines all areas of IRSN support and on an annual protocol which details actions to be accomplished by IRSN.

IRSN personnel support is mainly in the area of preparation of inspection programme, and assessment of inspection results. Moreover, IRSN specialists also often directly support ASN inspectors in the position of technical advisors in the course of inspections.

ASN inspectors are sometimes invited to participate in inspections performed by Department of nuclear security of the Ministry of ecology, sustainable development and energy. A suggestion of the IRRS team related to the safety/security interface is given in chapter 12 of the Report.

ASN performs also joint inspections in cooperation with regulators from neighbouring countries.

In addition to items in annual inspection plans, ASN performs evaluations of the licensees' performance (monographs). Monographs give guidance for assessment of inspections.

In addition to periodic planned inspections described in ASN inspection programme and guidance documents, ASN reactive inspections are performed when necessary. The majority of these reactive inspections are performed to follow up events. The general methodology for implementing a reactive inspection is described in ASN guidance documents; however, there are no comprehensive detailed criteria for initiating reactive inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team noted that while ASN does perform reactive inspections as a response to significant events, the decision to perform such inspections is done on case by case basis. There is no set of criteria for decisions on reactive inspections in ASN documents.*	
(1)	**BASIS: GSR-1, Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced."*
(2)	**BASIS: GS-G-1.3, Para. 3.10 states that** *"Reactive inspections, by individuals or teams, are usually initiated by the regulatory body in response to an unexpected, unplanned situation or incident in order to assess its significance and implications and the adequacy of corrective actions. A reactive inspection may be occasioned by an isolated incident or a series of lesser events occurring at the particular facility under consideration. Similarly, a reactive inspection may be made in response to a generic problem encountered at another plant or identified by the review and assessment staff of the regulatory body. Unlike planned inspections, which are scheduled, reactive inspections are only partly subject to planning by the regulatory body and may disrupt regulatory programmes and schedules. The regulatory body should assume that there will be a need for reactive inspections and should plan to meet its needs for staff and consultants accordingly. For example, in implementing the inspection programme, the regulatory body should establish a graded approach in responding to unforeseen circumstances. All available resources may be needed in responding to a serious event, whereas in the simplest of cases only one inspector may be needed. This pre-established graded approach in responding to*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	special circumstances will assist in determining the appropriate level of resources for use in inspections."
S9	**Suggestion: ASN should consider developing a set of internal guidance criteria for initiation of reactive inspections.**

A formal ASN letter is sent to the operator before announced inspections. Upon completion of the inspection, results are presented to licensee management during an exit meeting. During this meeting, for BNIs, the main inspection findings are signed-off by the lead inspector (pilot of the inspection team) and representative of the licensee. Results of inspections are officially reported to the licensee through a follow-up letter which contains the legal basis for the inspection, the date and place of the inspection, the scope of the inspection, a summary of inspection findings, required corrective actions and their legal basis, complementary demands and finally, observations. Detailed guidance on preparation of follow-up letters is given in the ASN document "Follow-up letters" (SMQ/DEU/QTL/INS/ASN/000302/2011).

Follow-up letters and documents related to enforcement actions are published on the ASN website, with the exception of enforcement documents related to labour inspections.

In addition to the follow-up letter, an ASN internal inspection report is prepared for each inspection. This report contains information on inspection participants, places visited, documents used or referenced for the inspections, significance of findings, comments on application of requirements, strong points and weak points found, points to be mentioned at national level, verification of the status of former corrective actions, and comments on what planned items of inspection were not accomplished. Guidance on preparation of inspection reports is provided in the form of a template.

7.1.3. INSPECTORS

In ASN, there are 280 inspectors implementing its inspection program. ASN inspectors are located at ASN HQ in Paris (117) and at the 11 regional ASN offices (163). ASN does not have resident inspectors. Approximately 800 inspections in BNIs and 1,200 inspections in other facilities and activities using ionizing radiation are performed each year. Most of the inspections are announced; however unannounced inspections are conducted as well. All inspections are carried out directly by ASN inspectors and cannot be delegated.

ASN inspectors can, at any time, visit BNIs and monitor the transport activities of radioactive substances as well as the warehouses, parking, loading or unloading facilities of radioactive substances.

To ensure effective implementation of the inspection program and enable the identification of significant issues, ASN emphasizes the training and qualification of its inspectors. The competence of inspectors is achieved through a well-developed systematic formal training program. There are several types of inspector specialisation in ASN: radiation protection inspectors, labour inspectors, pressure equipment inspectors and transport inspectors. The training programme is comprised of several modules, some general and obligatory for all inspectors, and other tailored to the needs of specific inspectors' specialisation. One person can be qualified for several inspector specialisations.

Newcomers must successfully complete a core business basic training module, a common nuclear safety technical training module, and other specific technical training modules. They must also obtain work experience through observation and participation in ASN inspections.

Inspector training is completed with an accreditation. Qualified inspectors must also complete mandatory in-service training modules and work experience modules. These modules comprise areas such as training on new regulatory requirements, handling of events, organisational and human factors, or safety of PWR refuelling.

The implementation of the training program is followed closely by the individual inspector's supervisor.

ASN applies several tools to harmonize the activities of the inspection staff including standardized procedures, inspection records templates and periodic observation of the inspectors by management.

There is a practice to change positions within French state administration every 4 years. This practice brings a high demand on the training process within the ASN.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

All general inspection principles described above are valid for inspections at NPPs. ASN performed 369 inspections at 58 reactors plus EPR in 2013. The IRRS team observed that the number of inspections performed and ASN staff's onsite presence are relatively low. However, sufficient number and quality of inspections are priorities of ASN Strategic plan for 2013-2015.

The IRRS team noted that as a result of an internal self-assessment, ASN has initiated improvements of its inspection program and planning process (Action item 7.2 in the ASN Self-Assessment Action Plan). These improvements include, e.g., improvement of existing inspection guidance with the goal to account for recently issued ASN regulatory requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team noted that, there has been no complete analysis to ensure that all inspection areas listed in IAEA GSG IAEA GS-G-1.3 appendix are covered in the ASN inspection programme.*	
(1)	**BASIS: GSR-1, Para. 4.50 states that** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body, …"*
(2)	**BASIS: Appendix to the GS-G-1.3 provides a list of** *"inspection areas to be inspected in the course or regulatory inspections."*
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.**

The IRRS team reviewed in details and discussed with ASN counterparts ASN document "ASN/INS/210 – Areas of periodic inspections at NPPs". This document defines inspection areas and topics, and provides also frequencies of inspections for majority of topics. The IRRS team also reviewed ASN intranet tools used to track the status of available inspection guidance documents. It was noted that inspection guidance does not exist, or is outdated, for some of inspections in the ASN/INS/120.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team noted that internal guidance for some of inspections within the NPP operational stage periodic inspection programme is missing or outdated.*	
(1)	**BASIS: GS-G-1.3 Para. 4.1. states that** *"To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail."*
S11	**Suggestion: ASN should consider completing its internal documents to provide guidance for all inspection topics and update existing inspection guides.**

Monographs for NPPs give guidance for assessment of inspections in the form of specific questions to evaluate status of barriers, policy, organisational and human factors, safety management, safety culture, etc. Results of those evaluations allow for trending of safety performances of each NPP and are also annually summarised at the national level as a source of information for establishing inspection priorities and other ASN activities.

The IRRS team reviewed also ASN resolution 2014-DC-0417 of January 2014 concerning the rules applicable to basic nuclear installations (BNI) with regard to the management of fire risks, the current inspection guide "Fire Risk Inspection Guide" (4-SD-GI-20), and the new draft version of this guide (SMQ/DRC/QUI/INS/ANS/000XXX/2014) which were used for the inspection at the Nogent NPP.

The IRRS Team visited the Nogent NPP, met with plant management and observed inspection performed by ASN regional inspectors.

The IRRS Team observed two regional inspectors performing their inspection focused on fire risks. The inspection consisted of reviewing of licensee's internal documents and software tool used for tracking of combustible materials as well as performing a walk down at the NPP Unit 2 nuclear auxiliary building.

ASN inspectors followed the inspection guide which describes in details items to be verified during of fire risk inspection. The IRRS team was informed that the head of the inspection was involved in preparing a new, more detailed inspection guide which will address the previously mentioned ASN resolution on fire risks. This new inspection guide was tested in the course of inspection.

ASN inspectors checked the licensee's tracking system (database), and compared the status of combustible materials declared in the database with the actual status in the NPP. The inspection also included reviewing the implementation status of modifications, operational experience feedback issues and the status of ASN requirements sent to the licensee as a result of previous inspections in the fire risk area. During the walk down, several non-compliances were identified in the licensee's combustible materials tracking system. Non-compliances revealed during the inspection were recorded by ASN inspectors, discussed with licensee staff during the walk down and communicated to the NPP manager during the exit meeting.

The IRRS Team discussed the relationship between ASN and NPP with the plant manager and the head of safety and quality mission. Plant management confirmed that ASN inspectors are considered to be competent, professional, respected and well prepared for inspections. When

asked about the most important safety issues at the Nogent NPP, the plant manager quoted ASN inspections findings listed in the ASN 2013 Annual report.

The Flamanville 3 NPP is in advanced construction stage in France. The construction stage inspection programme is in place and covers all inspection areas which are recommended to be covered by IAEA GS-G-1.3 guide. The commissioning stage inspection strategy is under preparation and is ready for commissioners' approval. The development of the inspection program will be initiated after approval of the strategy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team noted that inspection strategy and inspection programme for new build NPP nearing commissioning stage are not prepared yet.*	
(1)	**BASIS: GSR Part 1, Para 4.52 states that** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections."*
(2)	**BASIS: GS-G-1.3, Appendix sets out** *"inspection areas and stages of NPPs authorisation process, including siting stage, that to be subject to regulatory inspections."*
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.**

No inspections were performed at Flamanville 3 during the siting stage , the position of ASN staff is that site characteristic and other inspection topics quoted in the above mentioned IAEA guide have been covered by ASN review and assessment activities. There is also legal constraint, as ASN can perform inspections only at license holder premises, and inspections focused on siting would at least partially performed before siting license issuance (authorisation decree). The legislative framework part of the issue is covered in the Chapter 1 of the Report.

ASN counterparts informed the IRRS review team that ASN inspectors can perform regulatory inspections only in the area of BNIs. To ensure effectiveness of inspection related to NPPs, it is necessary to also verify activities done by EDF HQ departments, e.g. OEF process. A recommendation/suggestion of the IRRS team related to this issue is given Module 1 of the Report.

7.3. INSPECTION OF RESEARCH REACTORS

The inspection framework for RRs is the same as those for other BNIs. ASN has an internal procedure to select inspection themes and particular items. The procedure ASN/INS/202 'Periodic Inspection Theme for Non-NPPs' is available and it has been updated. It considers the safety importance of nuclear facilities, and categorizes nuclear facilities into 5 classes. The number of annual inspections is set in by considering current condition, capacity, and safety significance of the reactor. The procedure also describes inspection items and the core number of inspection on each item to perform for each facility. The items are ordered in accordance with the structure of the "BNI order". The IRRS team confirms that the ASN inspection procedures are up to date and reflect necessary changes.

More than 10 periodic inspections have been conducted above 2013 at the 'High Flux Reactor' in Grenoble, Each individual inspection were scheduled in the annual inspection programme of the previous year and the theme and lower items were arranged to cover operational activities. The proposal and schedule of inspections is delivered to research reactor utility through ASN official letters. An IRRS team review observed ASN's onsite inspection activity and that it was carried out according to procedures.

7.4. INSPECTION OF FUEL CYCLE FACILITIES

The framework of inspection for FCFs is the same as those for other BNIs. ASN"s department of environment and emergency department (DEU) coordinates the development of the annual inspection programme for FCFs as a part of annual inspection programme for BNIs. ASN draws up an annual programme of inspections based on various themes including criticality, radiation protection, fire protection, etc.

ASN inspectors from regional divisions and headquarter perform approximately 120 inspections of FCFs per year (including both announced and unannounced inspections) For example, approximately 55-60 inspections are performed at La Hague site each year. ASN also conducts an inspection on management of safety for the La Hague plant at least once per year.

The IRRS team observed a thematic inspection on radiation protection during the site visit to La Hague on November 19, 2014. For announced inspections, the inspection agenda is usually sent to the operator about two weeks before the inspection date. In accordance with the agenda, the operator prepares materials and presents information relevant to the agenda. ASN inspectors were well supported by IRSN expert on technical issues all through the inspection. The inspection was conducted in a very systematic way with an entrance meeting, detailed presentation by operator on important activities done and discussions, review of documents and records, site visit, discussion on potential issues, and an exit meeting.

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

The general framework of an ASN inspection in Radioactive Waste Management Facilities is the same as those for other BNIs.

The IRRS team observed the 19th November 2014 inspection at the "Centre de Stockage de l'Aube" (CSA). This thematic inspection on "Controls and periodic tests" was carried out by two ASN inspectors from the ASN Regional Division "Champagne-Ardennes" together with an expert from IRSN specialised on the safety of disposal facilities. The ASN inspectors have permanent access badges for their inspections.

The CSA licensee (ANDRA) was represented by the site director, the Security and Radiation Protection responsible and several ANDRA's technical experts (specialised in aspects related to maintenance and testing). The inspection was divided mainly in two parts:

- a meeting covering the following topics: practical organization of the licensee (in particular in relation with the activities of maintenance and periodic testing of components important for the safety of the installation), verification and clarification of licensee's procedures in the field of maintenance and periodic testing, an illustration of the tool used by the licensee to carried out the daily follow-up of its maintenance and testing planning/programme, a verification of the updating and functioning of the licensee's tool on the basis of practical cases selected by the inspection team;
- a visit to observe on-site compliance between the maintenance/periodic testing operations and the written procedures.

The inspection team was well prepared and carried out an in-depth inspection/verification including obtaining complete information and full clarification from the licensee on questions raised and on the practical on-site implementation.

Clear and univocal agreement between the inspection team and the licensee on the findings of this inspection concluded the visit.

7.6. INSPECTION OF RADIATION SOURCES FACILITIES

ASN carries out inspections on all aspects of radiation protection of both medical and non-medical uses of radiation. The inspectors are organised into Regional Divisions, and undertake inspections in their own geographical region e.g. Bordeaux Division, Paris Division, Dijon Division etc. The Regional Divisions are assisted by the Transport and Sources Department (DTS) and the Ionizing Radiation and Health Department (DIS) at the ASN Headquarters. DTS and DIS provide expertise in specialist areas such as cyclotrons and medical physics. Normally DIS does not undertake inspections on its own of medical sources, but DTS undertakes inspections on its own of source suppliers.

In general the inspection programme is commensurate with the graded approach for non-medical sources, but only for high activity sources. For non-medical sources the inspection programme is such that only the high risk sources have a defined inspection frequency. The lower risk sources do not have a defined inspection frequency and are only inspected according to the available resources. The inspection activities of lower risk sources are limited by the amount of available resource. However these sources are not exempted and should still be subject to inspection activities. For medical sources, the graded approach for the inspection programme is less clear. The approach in the medical and non-medical inspection programmes should be harmonized on inspection frequencies based on radiation risk associated with the activity or facility.

ASN should ensure that adequate resources are available for inspection of the low risk sources. Suggestion to deal with the resources issue is given in the Chapter 3 of the Report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team noted that the principle of graded approach is not consistently applied in all aspects related to the inspection of radiation sources:* - *For radiation sources, only high activity sources and other high risk radiation generators have a defined inspection frequency, and lower activity sources are only inspected subject to available resources* - *Inspection activities in the medical and non-medical areas do not appear to be fully harmonised in accordance with a graded approach.*	
(1)	**BASIS: GSR Part 1, Requirement 29 states that** *"Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity in accordance with a graded approach".*
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.**

During the course of the IRRS mission, IRRS members accompanied ASN inspectors on two inspections of sources and facilities. The first inspection was of a nuclear medicine department in

a Paris hospital, and the second inspection was of an industrial radiography practice in the Paris region, including transport of sources.

MEDICAL PRACTICE SITE VISIT

The IRRS team visited a local hospital to observe ASN staff conduct an inspection of a nuclear medicine department. The inspection was conducted by two inspectors from ASN regional division, and the scope of the inspection was on occupational exposure, medical exposure, waste and effluents. The inspection included areas such as staffing levels, qualifications and training, radioactive source management, the radiation protection programme including an overview of the duties of the radiation protection officer (PCR), safety and risk assessment, monitoring and categorization of workers in the workplace, the medical physicist program, QA and QC, justification and optimization, records, health surveillance and program for radioactive waste management. The inspectors had a comprehensive inspection list where follow-up issues from the last inspection were included.

The inspection was preceded by an opening meeting with the hospital management. This was followed by interviews with the management and relevant staff, including the PCR and the medical physicist. The inspectors then proceeded to a visual inspection of the nuclear medicine department, relevant rooms in the radiation therapy department, relevant rooms for solid waste storage and systems for hospital liquid effluent. The inspection concluded with an exit meeting where the main findings of the inspection were presented and discussed with the hospital management.

During the medical site visit, it was observed that the ASN inspectors had personal dosimeters, but no radiation measuring device for performing any independent radiation measurements. It was observed that the inspectors queried the classification of a particular zone in the nuclear medicine department, which may have been easily checked if an appropriate handheld radiation monitor was carried by the ASN inspectors.

The inspectors of ASN conducted the nuclear medicine department inspection in a professional manner and had a cooperative attitude. In a separate discussion with the hospital management and relevant staff, the IRRS team concluded that the hospital staff found the inspection process was valuable and important to increase the level of radiation protection safety in the department. However, the hospital staff expressed a desire for a more flexible and less time consuming authorization process regarding change of equipment, change in source activities, etc. They also made the comment that there were too many guidelines. It was note by the IRRS ream that ASN does not have the legal right to access documents with patient information or enter the treatment room if there is a patient inside during their inspection.

INDUSTRIAL RADIOGRAPY SITE VISIT

The IRRS team visited “PLS Controle facility” which uses radiation sources for Non-Destructive Testing (industrial radiography). The aim of this visit was to observe ASN staff conduct an inspection. The scope of the inspection was on radiation protection of workers and it included areas such as organization and scope of the programme, training and instruction of workers, safety and security systems, and categorization of workers and workplaces.

The inspection started with a presentation of the scope of the visit and was followed up by a round table discussion/interview with management, the licensee (PCR as employee), and other relevant staff. The inspectors then proceeded to conduct an inspection of three radiography installations (X-ray Generator, Ir-192 and hotcell for reloading sources into gammagraphy devices), and to conduct a practical observation and assessment of how the staff in the facility

conduct their activities. The ASN inspectors conducted the inspection in a professional manner and had a cooperative attitude with the relevant staff of the licensee (PCR).

Following the observation, an exit briefing was conducted with the licensee and relevant staff of the facility and findings of the inspection were presented and discussed at the exit meeting.

During a site visit, it was observed that the inspectors had no radiation measuring device for performing any independent verification measurements. The review of radiation measurements was based on the report of the accreditation laboratories. The accreditation is given by ASN.

It was also observed that the authorization is given to an employee rather than the legal entity.

In a separate discussion, the licensee and the management representatives expressed a desire for more dialogue with ASN such as through meetings regarding radiation safety and regulatory aspects, and also regarding the authorization system.

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

There are several BNIs in decommissioning stage in France. The inspection programme and guidance for decommissioning stage is of a similar structure as for BNIs operation stage and takes into account specifics of decommissioning activities.

About 70 inspections are annually carried out on installations currently in a decommissioning phase. Typical inspection themes include topics such as static and dynamic confinement; state of the systems, materials and buildings; waste; radiation protection; human and organizational factors and delicensing.

In depth inspections (inspection de revue) in the area of decommissioning have been carried out in 2013 on two EdF sites (St Laurent A and Chinon A: 5 UNGG-reactors) by 11 ASN inspectors and 5 IRSN experts.

7.8. INSPECTION OF TRANSPORT ACTIVITIES

ASN's responsibility for inspection of the transport of radioactive materials is specified in the Environmental Code. ASN's transport inspection activities encompass inspection of transport operations, package design testing, package manufacturing including fabrication and non-destructive testing, package maintenance, transport worker training, and radiation protection program requirements. ASN has developed a comprehensive set of guidance documents for inspection of transport, which cover a wide range of activities. Additional new guides are also under development.

ASN completed 131 transport inspections in 2013. Transport inspections are performed by ASN headquarters Direction du transport et des sources (DTS) staff and regional Division staff. Transport inspections can be announced or unannounced, and can be planned or reactive. An inspection plan is issued each year which identifies goals for the total number and priority topics for inspection. It was noted in the 2014 inspection plan that "During the course of 2014, two "transport" qualified DTS staff members are liable to leave ASN, which could affect the number of inspections run by DTS for the divisions (15 in 2013)." At present, the headquarters DTS staff responsible for transport includes the Director, Deputy Director, and six engineers, and the Divisions typically have one inspector each, who specializes in transport. Though some Divisions may have two inspectors, they would specialize, one for BNIs and the other for small scale nuclear activities. Transportation training is usually offered once per year, which can result in significant delays in completing the training. ASN identified maintaining inspector competence as action item 7.1 in the Self-Assessment Action Plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In the Divisions, the number of inspectors for the transport program is limited. It was observed that due to the limited number of inspectors in a Division, the transport inspections can be significantly impacted when an inspector is ill or otherwise unavailable. Additionally, there is a high turnover among the staff, which can lead to the Division having no inspector fully competent to inspect transportation at some times. Because the transport training is only offered about once per year, there can be a delay for getting the new inspector trained.*	
(1)	**BASIS: TS-R-1, Para. 307 states that** *"The competent authority is responsible for assuring compliance with these Regulations. Means to discharge this responsibility include the establishment and execution of a programme for monitoring the design, manufacture, testing, inspection and maintenance of packaging, special form radioactive material and low dispersible radioactive material, and the preparation, documentation, handling and stowage of packages by consignors and carriers, to provide evidence that the provisions of these Regulations are being met in practice."*
(2)	**BASIS: TS-G-1.5, Para.2.13 states that** *"The competent authority should establish and maintain a programme for training its own employees. The training provided should be sufficient to ensure consistency in the application of the Transport Regulations."*
S14	**Suggestion: ASN should consider developing a more effective training to address the limited number of transportation inspectors and the turnover in the Divisions.**

7.9. SUMMARY

The IRRS team concluded that there are sufficient legal basis and ASN internal documents to carry out regulatory inspections in accordance with relevant IAEA documents.

- ASN inspectors are well qualified, motivated to discharge their duties, and respected by inspected organisations. ASN has implemented a well-structured, systematic and effective system of inspectors' training,
- ASN inspections are planned and performed in such way that an acceptable level of assurance that regulatory requirements are met is achieved,
- Results of ASN inspections are recorded and communicated to the public, the inspected organisations and within the ASN, as appropriate.

The IRRS team identified several suggestions for improvement of ASN inspection programme and practices, for example the completion and updating of inspection guidance documents and the development of criteria for initiating reactive inspections.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

ASN is empowered to impose corrective measures and enforce their adoption, including sanctions in case of failure to observe the measures, by the Environment Code, the Public Health Code and the Labour Code. The Environment Code makes provisions for penalties, which comprise fines and prison terms, depending on the nature of the violation. ASN can also set penalties for activities regulated by the Labour Code and the Public Health Code.

ASN has a range of tools at its disposal:

- oral notices /remarks made by the inspector
- official letter from the ASN departments or general director
- formal notice from ASN to meet certain conditions within a given timeframe
- administrative penalties (after formal notice) and penal sanctions.

When some of the conditions imposed on the licensee of an installation or the person responsible for the activity are not respected, ASN sends a notice to the concerned party to meet these conditions in a given period. If the notice has not been complied with, in BNIs, ASN can take the following enforcement actions depending on the significance of the non-compliance identified:

- oblige the licensee to deposit in the hands of a public accountant a sum covering the total cost of the work to be carried out;
- have the work or prescribed measures carried out as matter of course and the expense of the person served a notice;
- suspend operation of the installation or execution of the operation in question; this measure is repealed as of right as soon as the imposed conditions are completely fulfilled.

For activities using ionizing radiation, following a formal notice, ASN can only suspend the authorisation, temporarily or definitively.

In the event of an “emergency jeopardizing human safety”, a “threat to public health and safety or to the protection of nature and the environment” or “severe imminent risks” ASN can issue interim prescriptions or administrative measures, for example to suspend operation of an installation or execution of an operation.

The individual inspector does not have the authority to take on-the-spot enforcement actions. Administrative action is initiated on proposals from the inspectors and decided by the ASN commission. Licensee can present its comments to the commission.

The inspectors are obliged to notify all crimes and offences of which they became aware in the performance of their duties. When an infringement is confirmed (for example by a second inspection) it’s the task of the ASN division to contact the services of the Public Prosecutors Offices, to provide the violation report and to inform them of the roles and prerogatives of ASN.

The initial training of inspectors has a specific module that includes the study of ASN "sanction" process and case studies. Enforcement actions implemented in ASN regional offices are discussed in an internal network that includes one member from each ASN service (regional office and department); these actions are also discussed between ASN service managers at the quarterly meeting. The goal of this process is to achieve a higher level of consistency. ASN performs an annual synthesis of its enforcement measures. It is an ASN objective to meet the public prosecutors’ department regularly to discuss and promote the efficiency of the enforcement process.

ASN has identified during the self-assessment that there is a need to strengthen its enforcement tools to make them commensurate with the significance of the non-compliance (graded approach) and with the attitude of the operator. Currently, ASN cannot impose significant fines on the operator of a facility. ASN took action on this topic. ASN transmitted their needs and proposals to the responsible ministries and the current situation will be improved with the new Energy transition and green growth bill which is currently in the stage of discussion in the Senate.

Nevertheless the IRRS team is convinced that there is a strong need to improve the enforcement tools ASN can use. The additional tools proposed by ASN for the new energy transition and green growth bill seem to be adequate to improve the ability for ASN to enforce the mandatory activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team noted that there is a need to strengthen ASN enforcement tools with the objective to make them commensurate with the significance of the non-compliance (graded approach) and taking into account the response of the operator. Current legal basis is not sufficient for gradation of sanctions.*	
(1)	**BASIS: GSR Part 1, Para 4.54 states that** *"The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach."*
(2)	**BASIS: GS-G-1.3, Para 5.13 states that** *"The regulatory body should have the authority to impose or recommend penalties, such as fines on the operator as a corporate body or on individuals, or to institute prosecution through the legal process, depending upon the legal system and authorization practices in the State concerned. The use of penalties is usually reserved for serious violations, for repeated violations of a less serious nature or for deliberate and wilful non-compliance. Experience in some States shows that imposing penalties on the organization rather than on individuals is preferable and is more likely to lead to improvements in safety performance."*
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.**

8.2. ENFORCEMENT IMPLEMENTATIONS

Regarding the implementation of enforcement, ASN and their inspectors' rights are given by the Environment Code, the Public Health Code and the Labour Code. In general, inspectors are empowered to demand curative, preventive and corrective actions.

ASN uses its enforcement tools (administrative actions and sanctions). In 2013, ASN has presented 36 violation reports and 18 administrative actions. Eight violation reports were related to BNIs (excluding labour inspections). 16 compliance notices were issued to BNIs. For the small scale nuclear activities, ASN issued 16 violation reports and one administrative action (suspension of the activity).

The fundamental principles applied by ASN when determining enforcement measures are described mainly in the following documents:

- ASN enforcement policy paper
- Means of enforcement and sanctions (ASN/SAN/01)
- Principles applied by ASN (ASN/SAN/02)

ASN can take appropriate enforcement actions in situations where an immediate health or safety concern has been identified. If inspectors find a serious non-compliance and there is a threat to humans or the environment, the inspectors are expected to provide a warning to the inspected person and are required to inform senior ASN management immediately.

ASN inspectors are required to provide an inspection follow-up letter. This letter has to be sent to the licensee to request to sort out detected non compliances. The operator is expected to answer the follow-up letter within two months. If the operator doesn't comply within the given timeframe the inspector can propose to take decision on conducting enforcement measures. ASN has clearly recognized that to assist the decision of the inspector, a well-structured procedure including criteria and examples from the past experience is needed. ASN is revising the current procedure (ASN/SAN/02) to give essential guidance to the inspector.

ASN presented the new version of this procedure to the IRRS team (draft ASN/SAN/120 and ASN/SAN/122). The basic principles mentioned there are:

- assessment of the seriousness of the non-compliance
- evaluation of the licensee factor

The first step of the procedure is to assess seriousness of the non-compliance. The draft contents a guidance including a list of topics to consider. The non-compliance is classified as minor, significant, important or major. For NPPs, guidance on the tolerable duration for the correction of specific safety-relevant deviations which are not formally in the scope of regulations nor in the scope of technical specifications is being prepared since January 2013 (Action item 8.2. in the ASN Self-Assessment Action Plan). The content of the guide was discussed with stakeholder within an intensive consultation process.

The second step is to determine the basic enforcement measures and sanctions. For this step, the draft contents a list of examples from the past and proposals for adequate ASN actions for different types of installations and activities.

The third step is to evaluate the licensee factor. For this step, the draft contents a list of criteria to evaluate the behaviour of the licensee in the past and during the evaluation of the non-compliance.

The final step is to check once again the intended enforcement action with respect to contextual and strategic factors.

The IRRS team states that the main elements of the presented draft are reasonable. The intended procedure is suitable to support the decision of the inspector.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ASN has documents for enforcement actions in place. ASNs self-evaluation states that ASN/SAN/02 document is difficult to use, not applicable for all situations, and therefore is being currently revised. There is an action in ASN action plan to revise ASN/SAN/01 document. The IRRS team noted that also related policy document does not give a clear description of enforcement main principles and should be revised as well.*	
(1)	**BASIS: GSR Part 1 Para 4.58 states that** *"The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary."*
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.**

8.3. SUMMARY

Based on the interviews and the review of the documents presented, the IRRS team states that ASN is empowered by the Environment Code, the Public Health Code and the Labour Code to impose corrective measures and enforce their adoption, including sanctions in case of failure to observe the measures. For this ASN has a range of tools (administrative measures and sanctions) at its disposal.

ASN has identified in the self-assessment that there is a need to strengthen their enforcement tools with the goal that enforcement tools be commensurate with the safety significance of the non-compliance. The IRRS team strongly supports the results of the ASN self-assessment. In addition the IRRS team suggests that ASN should revise their basic internal documents to support the inspector's decisions on enforcement measures as appropriate.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The French regulatory system comprises a comprehensive framework of laws, decrees, orders, ASN decisions (generic resolutions and facility specific decisions) and ASN guidelines. The laws are established by Parliament and grant powers to the Executive (Government) to develop and promulgate decrees and orders. These are intended to be of a general nature, but the Government is not fettered in this respect. ASN must be formally consulted during the development of decrees and orders relating to its areas of regulatory responsibility and indeed may help to draft them.

The Government exercises regulatory powers. It is therefore in charge of laying down the general regulations concerning radiation and nuclear safety. The Code of Environment (previously TSN Act) lays down principles such as the protection of major interests (notably public health and safety, as well as the protection of nature and the environment), the prime responsibility of the licensee for the safety of its facility and the public's right to reliable and accessible information on nuclear safety. The legislative part of the Public Health Code provides e.g., that activities incurring a risk of exposure of persons to ionizing radiation must satisfy the principles of justification, limitation and optimization. Worker occupational exposure is regulated via the Labour Code and associated regulations.

The Government has issued about fifteen decrees. For example, Decree of November 2, 2007 is related to regulation of Basic Nuclear Installations (BNI) and transport of radioactive materials. The General Rules for BNIs have been promulgated via a Ministerial "BNI Order of February 7, 2012". This is an umbrella document which defines the high level principles that must be met, e.g. defence in depth, requirements for deterministic and probabilistic analysis. It updates previous regulatory provisions and adds new provisions. Decrees, orders and resolutions are mainly applicable to all nuclear installations, leaving the use of graded approach in their implementation phase.

The Code of environment also establishes the basis for ASN to issue decisions. These decisions can either be generic resolutions or specific decisions for only one facility. In 2008 ASN defined a project for developing new regulatory resolutions and guides which clarify the decree and order setting out the general rules applicable to BNIs. About fifteen ASN regulatory resolutions will detail some of the conditions of application of orders and decrees for various subjects. A couple of technical resolutions have already been issued (e.g. fire protection) and several are under development. The project has been significantly delayed. The main reasons have been the waiting period for ministerial orders to be published and the resources shifted to follow-up the Fukushima Daiichi accident. Current goal is to finalize the project in 2015.

Once completed, ASN resolutions and guides will cover all stages of the lifetime of BNIs (siting, design, construction, commissioning, operation, decommissioning and release from regulatory control) and will have a scope of a comprehensive set of topics related to safety. Siting phase is covered by creation authorization (see Section 5.1) and related requirements include e.g. external hazards and characteristics of the site and its environment. New sites are not considered for NPPs, but siting issues might be relevant to other BNIs (see Section 9.5).

There are some topics which are currently missing from the French regulations, such as operating rules (see Section 9.2), but will be covered after finalization of the project for new resolutions and guides. More detailed resolutions or guides are being developed also for reporting of operational events (see Section 2.2), management system requirements and contents of SAR (see

Section 9.3), ageing management and human factors (see Section 9.4), waste management (see Section 9.5), and content of emergency plans (see Section 10.3).

Concerning the safety principles and associated criteria, the French regulations set a limit associated with the impact to the public of the normal operation of an installation (1 mSv/y). For the analyses of incident and accidents, explicit limits for releases or dose limits to the public are not set in regulations but are addressed, in general terms, in the BNI order and technical guidelines. BNI Order sets a generic safety objective so that accidents that could lead to large releases or develop too rapidly to allow timely protective measures must be demonstrated physically impossible or extremely improbable with a high level of confidence. It also provides that the intensity of the radiological consequences is assessed "with respect to reference values expressed as levels of intervention of the public authorities". Current technical guidelines establish a qualitative objective, which for DBA is, "no necessity of protective measures for people living in the vicinity of the damaged plant (no evacuation, no sheltering)" (see Section 6.2.3). In the new resolutions, ASN is considering of requiring the licensees to define for each event class the reference values retained as objectives not to be exceeded in terms of potential consequences to the public. This means that the licensees will have to propose the appropriate criteria to the regulator.

The Law reserves for the Government the right to take major decisions concerning BNIs, for example agreeing to the construction of a new NPP or the start of decommissioning. Once the Government has granted an authorization for a specific installation, ASN may attach conditions to it following a public consultation. ASN varies these conditions during the lifetime of an installation in accordance with the stage of life e.g. commissioning, operation, decommissioning, etc. The most significant changes in conditions often occur following periodic safety reviews.

The process for developing and updating regulations and guides is described in the internal procedure ASN/REG/01 "General regulations". There are numerous checks and balances in the process, which include internal review, early stage meetings with licensees, consideration by the Commission prior to public consultation, further reviews and potentially consultation with a Standing Committee and the High Council for Technological Risk Prevention, and finally submission by the Commission to the responsible Minister for approval. At this point the minister can only approve or reject the resolution; the text itself cannot be modified. The process is thorough and may take several years to complete. However, the ASN procedure is quite generic and ASN should consider developing more detailed guidance.

The legally binding technical resolutions will be supplemented by a collection of ASN guides which present possible methods that ASN considers acceptable to fulfil current requirements; operators can nevertheless choose another option if they show that the solution they retain is as effective. Previously, ASN issued basic safety rules (RFS) which had a similar nature. The process for developing guides is more flexible and not all steps included in the resolution developing process are necessary (e.g. COREL review or public consultations). Licensee representatives can be included in the working group.

The process for the developing and issuing of resolutions includes numerous checks and balances in the process, including in particular public consultation. Furthermore, when consultations take place with other bodies such as Standing Committees or the High Council for Technological Risk Prevention, their opinions are also published regardless of whether they support or oppose the proposals. During the public consultation, the comments received are placed on the ASN website. One public consultation has resulted in thousands of comments. ASN subsequently explains how it has considered and responded to them. All resolutions and the opinions of the ASN Commission are published on ASN's "official bulletin" available on its website. ASN guides are published on the website, too.

ASN is committed for the implementation of WENRA Reference Levels. This may be achieved through laws, as is the case for the requirement for periodic safety reviews to be conducted every 10 years, or through decrees, orders, ASN resolutions or guides. ASN presented a matrix showing how each WENRA Reference Level is transposed into regulations or guides.

All binding regulations set out details of transitional arrangements, for example the dates on which they will come into force and whether these differ depending on whether they apply to existing or new facilities. The fulfilment of the regulatory guides is typically discussed in the next PSR of the facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The ASN project for developing new resolutions and guides has been significantly delayed. The IRRS team has been informed that the main reasons for delays have been the waiting periods for ministerial orders to be published and the resources shifted to follow-up the Fukushima Daiichi accident. Current goal is to finalize the project in 2016.*	
(1)	**BASIS: GSR Part 1, Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
R10	**Recommendation: The regulatory body should complete the project for developing technical resolutions and guides in a timely manner.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The guiding principle in France has been, as far as practicable, to develop regulations which would be applicable to all nuclear installations and activities, while allowing for a graded approach in their implementation. ASN has a possibility to clarify this in resolutions and facility/activity specific decisions. Currently, the use of the graded approach is not very clearly defined in the regulations and guides.*	
(1)	**BASIS: GSR Part 1, Para. 4.62 states that** *"The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach."*
S16	**Suggestion: The regulatory body should consider further clarifying the graded approach used in the regulations and guides for different facilities and activities.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Currently, the French general regulations for BNIs set only a high level safety objective for the provisions adopted by the licensee and general reference values for the analyses of consequences of incidents and accidents. In the new resolutions and guides, ASN is considering requiring the licensees to define for each event class the reference values retained as objectives not to be exceeded in terms of potential consequences to the public. This means that the licensees will have to propose the appropriate detailed criteria to the regulator.*	
(1)	**BASIS: GSR Part 1, Para. 4.62 states that** *"The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach."*
S17	**Suggestion: ASN should consider setting out, in the regulations or guides, explicit criteria related to the analyses of incidents and accidents.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The process for developing and updating regulations and guides is described in the internal procedure ASN/REG/01 "General regulations". The procedure is quite generic. ASN has already recognized the need for a separate procedure for developing guidelines but a more detailed guidance for developing resolutions could also be considered.* *The current procedure does not include regular assessment of the need to update the regulations or guides. In addition, although ASN uses IAEA safety standards for developing its national regulations and guides, the process to keep national regulations consistent with these safety standards as they evolve is not yet formalized. This was also recognized in the ASN self-assessment.*	
(1)	**BASIS: GSR Part 1, Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."*
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.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

NPPs are basic nuclear installations (BNIs). Most of the regulations are therefore the same as that for other BNIs (see Section 9.1).

A review of ARM related to the modules on "Safety of NPP: Design" and "Safety of NPP: Commissioning and Operation" revealed that the requirements of SSR-2/1 and SSR-2/2 are covered in generic terms in higher level documents (Code of Environment, Order of 7 February 2012). In addition, ASN makes reference to the technical guidelines for design and construction of the next generation of nuclear power plants with pressurized water reactors adopted during the GPR/German experts plenary meetings held in October 2000 which includes various aspects of IAEA Safety Requirements SSR-2/1. However, as a result of a gap analysis performed by ASN, some requirements of SSR-2/1 have not been addressed yet in the guidelines. In relation to the design requirements for NPPs, a draft guideline is being processed which should close the identified gap. IAEA Safety Requirements SSR-2/2 are currently not specifically covered in guidelines of ASN, though it is planned to address them in a new resolution on generic operating rules. With respect to NS-R-3, there exist requirements in the government Decree related to the hazards to be considered. Additionally, several guidance documents have been developed by ASN such as those for flooding, seismicity (earthquake), meteorology and man-made hazards as well as those for geological and geotechnical site analysis.

ASN has established the need to update and complete its regulatory framework by means of resolutions (legally binding) or guides (none legally binding). A programme has been set up grouping the topics that need to be covered in the main areas of: "organisation and responsibility", "safety demonstration", "control of inconveniences and the impact on health and environment", "nuclear pressure equipment" (completed), "waste management", "management of emergencies" and "particular dispositions". Some 15 regulations are at various stages of development. After the enactment of the 2012 Order on BNI, ASN has revised its plan to update and complete its guideline framework also taking into account the identified gaps with respect to the IAEA safety standards, especially SSR-2/1 and SSR-2/2.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

Research reactors are basic nuclear installations (BNIs). Most of the regulations are therefore the same as that for other BNIs (see Section 9.1).

In 2008, ASN defined a programme of regulatory resolutions and guidelines which clarify the decree and order setting out the general rules applicable to BNIs (see Section 9.1). However, more detailed resolutions or guides have not been published currently in some areas, such as quality assurance and contents of SAR.

There are many different features between nuclear power plants and research reactors. However French regulations are mainly implemented on the basis of safety principles of nuclear power plants and the application of the graded approach has been done through their implementation (see Section 9.1). Different features of neutron beam facilities, material experimental equipment and radioisotope treatment installations of research reactors should be reflected in the guidelines, which will be prepared in the use of the graded approach.

9.4. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

There are no specific regulations and guides for FCFs. Most of ASN decisions and guides for BNIs are applied to FCFs since all FCFs are categorized as BNIs. ASN decisions and guides which have been already published, those under public consultation, and those being drafted

cover the necessary safety issues for the lifecycle of FCFs (i.e., siting, design, construction, commissioning, operation, and decommissioning).

In 2008 ASN defined a programme of regulatory resolutions and guidelines which clarify the decrees and orders setting out the general rules applicable to BNIs (see Section 9.1). Currently, more detailed requirements are missing in some areas, such as those for ageing management and human factors which are important to the safety of FCFs.

The Code of Environment, article L.542-1-2, states that "reduction of the quantity and toxicity of radioactive waste is sought in particular by treating spent fuel and by treating and conditioning radioactive waste". Subsequently, the Ministerial decree 2007-1557 requires that a waste study to be submitted as part of the application for commissioning of BNIs. The waste study includes an analysis of the waste to be produced in the installation, and the waste zoning plan, the measures (i.e., sorting, packaging, treatment, storage and disposal) adopted by the licensee for waste management. This demonstrates that legal and regulatory framework actually require, at the design stage of BNIs including FCFs, the avoidance or optimisation of the generation of radioactive waste.

9.5. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

With regard to radioactive waste disposal, in addition to the already published legislation, ASN established specific basic safety rules for both deep geological disposal and near surface disposal of radioactive waste that are used to evaluate the safety of each type of disposal facility as:

- Basic Safety rule III.2.f, Safety guide on the permanent disposal of radioactive waste in deep geological disposals (February 2008);
- General Safety guidelines for site selection for the disposal of long lived, low specific activity waste (May 2008); and
- Basic Safety rule 1.2, safety objectives and design basis for surface disposal of radioactive waste (June 1984).

Basic Safety rule III.2.f sets forth that the individual effective dose calculated should not exceed 0.25 mSv/y for prolonged exposure related to for normal evolution scenarios. More specifically, it clearly states that indicators other than dose (e.g., flow or concentration of activity estimates for various locations in installation) may be used, which fully conforms to SSR-5 on alternative use of complementary safety indicators.

ASN is presently drafting a new decision about RW disposal facilities. The new WENRA reference levels for RW disposal facilities have been already integrated in this draft decision and will address aspects related to the authorization for closure of a disposal facility.

Many of general regulations and guides for BNIs are also applicable to RWMFs, however ASN has been drafting some decisions specific to predisposal management of radioactive waste as:

- Decision on waste storage facilities;
- Decision on packaging of radioactive waste; and
- Decision on study of waste management and summary of waste produces.

ASN also defined the principles to be followed by the radioactive waste producers from small scale nuclear activities in its Decision 2008-DC-095, which set forth that radioactive waste and effluent must be disposed of in authorised facilities, unless there are special provisions for on-site organisation and monitoring of their radioactive decay (this concerns radionuclides with half-life of shorter than 100 days).

ASN activities are also covering the requirements on the national policy for RWM (see Section 1.7). The requirements on the identification, control and minimization of RW are well addressed

in the Code of Environment and the Ministerial Decree 2007-1557. ASN applies a case-by-case process (based on the technical support of the IRSN) for the waste acceptance criteria. For example, the waste acceptance criteria for the CSFMA Disposal facility are updated by Andra and reviewed by ASN at every PSR or during inspections. A dedicated ASN resolution, in project, defines acceptance conditions for waste packages in all waste disposals.

The available regulations and guides may cover basic safety aspects of RWMFs, however radioactive waste safety issues should be more appropriately addressed once the regulations under development are will be published. Therefore, ASN decisions, which are currently being drafted, should be finalized without delay (see Section 9.1).

More specifically, ASN should consider preparing safety guides on the standard format and content of a Safety Case, site criteria, etc., related to the upcoming proposal from Andra of a near- or sub-surface disposal facility for LL-LL waste (e.g. radium bearing and graphite waste) in a timely manner (depending on the options to be proposed by Andra in 2015). ASN already published in 2008 a note about general safety orientations for site selection for the disposal of Long Lived, Low specific activity waste, but this general note has to be updated and completed with additional specific guides.

After this IRRS mission, France intends to request an ARTEMIS review of its policy on waste management and of its implementation; this is in order to address the requirement of the 2011 EC-directive about waste into national legislation and to review the National Waste Management Plan. It also intends to request a peer review of the safety option file transmitted by Andra regarding the deep geological disposal project. The French ARTEMIS-mission will be a pilot mission (the first of this kind to be organized by the IAEA). In the field of RWM, this ARTEMIS-mission (licensee oriented) will be complementary to the IRRS mission (regulatory body oriented). The IRRS review team encourages this ASN initiative.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In case Andra proposes a near-/sub-surface disposal option for LL-LL waste, ASN has neither specific expertise nor specific safety guides for the review of safety options or the application file.*	
(1)	**BASIS: SSR-5, Requirement 2 states that** *"The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process…"*
(2)	**BASIS: SSR-5, Para. 3.8 states that** *"General standards for the protection of people and the environment are usually set out in national policy or in legislation. The regulatory body has to develop regulatory requirements specific to each type of disposal facility for radioactive waste, including each type that is envisaged, on the basis of national policy and with due regard to the safety objective and criteria set out in para. 2.15. The regulatory body has to provide guidance on the interpretation of the national legislation and regulatory requirements, as necessary, and guidance on what is expected of the operator in respect of each individual disposal facility."*
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**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	manner (depending on the options to be proposed by Andra in 2015).

9.6. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITES

Regulations related to radiation sources are issued by the Ministries in charge of Public Health and of Labour. ASN contributes to drafting regulations by providing advice on draft decrees and ministerial orders. Although it appears that the level of review and assessment against these requirements is undertaken using a graded approach, commensurate with the risk of the activity, ASN does not appear to have documented this process (see also Section 9.1).

ASN develops and publishes guides on its website relating to radiation sources. These guides cover many aspects of radiation sources including design, the authorization process (how to make applications), management of wastes and uses of radiation in the medical and industrial fields.

ASN has made guidance available on its website on the use of radiation sources, in both medical and non-medical applications e.g. industrial radiography, sealed sources, medical and dental radiology and radiotherapy.

9.7. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

Dedicated provisions of the Code of Environment detail obligations of licensees and producers of spent fuel and radioactive waste for financing the safe decommissioning of their installations and safe management of their spent fuel and radioactive waste. Licensees and producers of radioactive waste and spent fuel have to assess prudently the cost of decommissioning, of reprocessing of spent fuel and of long term management of waste.

The regulatory framework in the field of decommissioning addresses all basic nuclear installations (BNI). The release of an installation from regulatory control depends on its final state. The Ministerial order of 7th February 2012 requires that the final state reached on completion of dismantling must be that it prevents the risks or inconveniences that the site may represent for the interests of the Code of Environment (L.593-1 of the Environment Code), particularly considering the projections for reuse of the site or buildings and the best post-operational cleanout and dismantling methods and techniques available under economically acceptable conditions.

Complementary to these provisions, ASN policy concerning the decommissioning and delicensing of basic nuclear installations in France and ASN guide n 6 define the expected final state as the state where all dangerous substances, including radioactive, have been removed from the BNI. In case of residual pollution and depending on the subsequent use of the site, ASN may condition the delicensing of the BNI to the implementation of public protection restrictions in application of decree 2007-1557 of 2nd November 2007.

In anticipation of dismantling, the licensee (Order of 7 Feb 2012) must maintain its knowledge of the installation and the technical and financial capacities allowing the dismantling operations to be carried out throughout completion, while protecting the interests mentioned in article L. 593-1 of the Code of Environment. In order to further guarantee that the licensee has sufficient knowledge of the installations and technical and financial capacities the ASN is involved in promoting a law that requires the operator to implement a strategy of immediate decommissioning and start as soon as possible the decommissioning operation of a shutdown facility. The IRRS team is supporting this initiative (which is also identified by the ASN as action 5.3 in its Action Plan).

In accordance with the decree 2007-1557 of 2 November 2007, all BNI licensees must prepare a draft decommissioning plan for this facility, at the time of its creation. This plan is to be updated throughout the lifecycle of the facility. The aspects related to the compliance with the end state criteria and controls if the site cannot be released from the regulatory control are addressed in section 5.7.

The regulatory framework doesn't define general criteria for the release of an installation and each installation is analysed on a case-by-case basis.

The IRRS team encourages the ASN to pursue its efforts in completing the project of developing technical resolutions and guides in the field of decommissioning and dismantling in a timely manner (see chapter 9.1 of this report).

9.8. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

The IAEA Regulations for the Safe Transport of Radioactive Material, TS-R-1, 2009 Edition, have been incorporated into the United Nations (UN) Recommendations on the Transport of Dangerous Goods, Model Regulations, and Eighteenth Revised Edition. The UN Model Regulations are then incorporated into the modal standards for road, rail, water, and air:

- European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);
- Regulations concerning the International Carriage of Dangerous Goods by Rail (RID);
- European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN);
- IMO International Maritime Dangerous Goods Code (IMDG); and
- Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions).

The Code of Environment, Legislative Part, Order no. 2012-6 of 5 January 2012 amending Books 1 and 5, is the underlying French law and identifies ASN's responsibility for the safety of the transport of radioactive materials. The modal standards, as identified above, which incorporate TS-R-1 are implemented in France through Orders.

TS-R-1 is very effectively incorporated into the French regulation with very little exception. The only area where some additional regulation was identified as being needed is to extend ASN's regulatory authority to transport carriers. It was identified that a decision required under the Public Health Code had been drafted but not yet adopted. The proposed decision would require notification of carrier's activities to ASN, making the radiation protection requirements of the Labour Code applicable to carriers of radioactive material. This was identified as action item 5.5 in the Self-Assessment Action Plan.

ASN has developed a comprehensive set of guidance documents, both for use by ASN staff and for applicants and licensees. As noted in Section 7.8, ASN has many guidance documents for inspection. These guides provide detailed information, for example text from the pertinent regulations, the agenda and common themes for the inspection, and detailed examples or checklists of items to be evaluated during the inspection.

For applicants and licensees, ASN makes key guidance documents available on the ASN website. Guides available on the website include Guide No. 7, for applications for shipment and package approval, and guidance for the reporting of transport-related incidents. ASN initial approvals and regulatory decisions are also publicly available on the website. ASN has appropriate regulations to include all requirements of TS-R-1 and adequate guides for implementation of the transport regulations by all modes of transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The decision to require notification to ASN for carriers of radioactive material which is needed to apply the radiation protection requirements of the Labour Code has not been adopted. This notification is important to ensure effective inspections of the radiation protection programmes for transport.*	
(1)	**BASIS: TS-R-1, Para. 302 states that** *"A radiation protection programme shall be established for the transport of radioactive material. The nature and extent of the measures to be employed in the programme shall be related to the magnitude and likelihood of radiation exposures. The programme shall incorporate the requirements of paras 301, 303–305, 311 and 559. Programme documents shall be available, on request, for inspection by the relevant competent authority."*
(2)	**BASIS: TS-G-1.3, Para. 5.14 states that** *"Certain requirements for protection and safety are so important that compliance with them should be independently verified. It is the principal role and responsibility of the competent authority to enforce compliance with all relevant requirements and standards, including those for the optimization of protection and safety in transport, by means of independent verification."*
S19	**Suggestion: ASN should consider completing the process to implement the Public Health Code to require notification by carriers of radioactive material.**

9.9. SUMMARY

The French regulatory system comprises a comprehensive framework of laws, decrees, orders, and ASN decisions and guidelines. In 2008, ASN defined a project for developing new regulatory resolutions and guides which clarify the decree and order setting out the general rules applicable to BNIs. Current goal is to finalize the project in 2015. Once completed, ASN resolutions and guides will cover all stages of the lifetime of BNIs and have a scope of a comprehensive set of topics related to safety. However, ASN should consider developing explicit criteria for radiological consequence analyses of incidents and accidents. ASN should also consider preparing a safety guide for sub-surface disposal facility if that facility will be proposed by Andra in 2015. In addition, ASN should consider further clarifying the graded approach used in the regulations and guides for different facilities and activities.

The process for developing and updating regulations and guides is quite generic. ASN has already recognized the need for a separate procedure for developing guidelines but a more detailed guidance for developing resolutions could also be considered. Currently, there is no systematic process for evaluating and reviewing regulations and guides (including the assurance of coverage of relevant IAEA standards), and revising them, as appropriate.

Currently, the Public Health Code does not define an administrative regime to apply radiation safety requirements specifically to carriers of radioactive material. ASN should complete the process to implement the Public Health Code to incorporate the notification requirement for carriers of radioactive material.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

In this section (module 10), all observations are based in part on the following requirements, contained in paragraphs 3.8 and 3.9 of GS-R-2.

The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. For a facility in threat category I, II or III, appropriate emergency [preparedness and response] arrangements shall be established from the time that nuclear fuel (or significant amounts of radioactive or fissile material) is brought to the site, and complete emergency preparedness as described here shall be ensured before the commencement of operation. The regulatory body shall ensure that such emergency arrangements are integrated with those of other response organizations as appropriate before the commencement of operation. The regulatory body shall ensure that such emergency arrangements provide a reasonable assurance of an effective response, in compliance with these requirements, in the case of a nuclear or radiological emergency. The regulatory body shall require that the emergency arrangements shall be tested in an exercise before the commencement of operation [of a new practice]. There shall thereafter at suitable intervals be exercises of the emergency [arrangements], some of which shall be witnessed by the regulatory body. In fulfilling its statutory obligations, the regulatory body […] shall establish, promote or adopt regulations and guides upon which its regulatory actions are based; [...] shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified).

Additional basis for suggestions and recommendations refers to safety standards contained in GS-R-2, GSG-2 and GS-G-2.1 and is noted in the appropriate tables.

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Basic responsibilities

The regulatory requirements in EPR that apply to operating organizations are issued by several organizations, including the ASN, the Ministry of Interior, the Ministry of Labour, and the Ministry of Environment (plus the Ministry of Energy on issues related to nuclear security). The basis for ASN's authority is established in Article 20 of Prime Minister Décret n°2007-1557 du 2 novembre 2007, which requires licensee of BNIs to submit onsite emergency plans (PUI) to ASN. Regulations relating to EPR related to incidents and emergencies involving radiation sources are administered by ASN. Transport EPR regulations are contained in a government order and are based on international regulations; ASN is the competent authority for verification. Based on document reviews, interviews and site visits, there is good evidence of a high and effective degree of cooperation between all regulatory authorities involved in EPR, and of integration of nuclear and radiological emergency planning with EPR for conventional emergencies.

ASN has full oversight of licensee's EPR arrangements for on-site response and for ensuring appropriate and effective interface with offsite authorities, with the exception of security and response to malevolent incidents. In this case, ASN interfaces with the ministry of energy.

The role of the licensee is clearly defined in a government order and is well aligned with the national EPR framework. This order requires operator to put in place an organization, physical and human resources and procedures for emergency situations in order to manage the situation, both for radiological and non-radiological risks, and to prevent, delay or limit offsite

consequences. The Public Health Code further defines the role of the operator with regards to EPR, including the interaction between the onsite and offsite organizations during an emergency at a BNI.

Assessment of threats

The operating organizations of basic nuclear installations (BNI), including NPPs and other nuclear facilities, must submit a safety analysis as part of the licensing process. This analysis is used to determine the level of emergency preparedness needed and the size of emergency planning zones. The ASN reviews and determines the acceptance of this technical assessment. The prefect ultimately determines the size and shape of the emergency planning zones, based in part on the opinion of the ASN, with the caveat that for NPPs, the distances are standard and are set at the national level. The PAZ, where deterministic effects are deemed possible, is deemed to be within the site, although this is not referred to in emergency plans. The equivalent of the UPZ is the reflex zone where urgent actions may need to be taken: 2 km for immediate evacuation in case of a fast kinetic event (release expected in less than 6 h), 5 km for evacuation and 10 km for sheltering and stable iodine. The threat/hazard assessment is not required to take into account severe accidents with uncontrolled releases. This is not fully consistent with international safety standards contained in GS-R-2. However, it should be noted that the national plan (developed with the advice of ASN), the ORSEC plan (generic for all emergencies) and the post-accident guidelines (developed under the leadership of ASN) take into account protracted releases and recognize that some protective actions may need to be taken beyond the planning zone. Furthermore, ASN is currently in discussion with other European countries (through WENRA and HERCA) to harmonize emergency planning zones and strategies taking into account a broad spectrum of possible emergencies.

There is a categorization scheme for all facilities and practices, based on the importance of the practice in terms of several factors, including the potential impacts of accidents. This hazard categorization is more refined than the example provided in GS-R-2. It is used to determine the level of EPR required, the frequency and extent of inspections, and the general degree of regulatory oversight required.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The level of integration of the regulatory framework for EPR between ASN and other government organizations with regulatory or legal authority over EPR is high, consultative and reflects a very good example of an all hazard approach.*	
(1)	**BASIS: GS-R-2 Para. 1.3 states that** *"[...] in order to be effective, the response to a nuclear or radiological emergency must be well co-ordinated and arrangements must be appropriately integrated with those for a conventional emergency."*
GP4	**Good practice: The regulatory and legal requirements for nuclear and radiological emergency planning illustrate a very high degree of integration and harmonization with other conventional emergency preparedness at the local and national levels.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The EPR threat/hazard assessment for NPP does not address the possibility of severe accidents with uncontrolled releases.*	
(1)	**BASIS: GS-R-2 Para. 3.15 states that** *"The nature and extent of emergency arrangements [...] shall be commensurate with the potential magnitude and nature of the threat associated with the facility or activity. The full range of postulated events shall be considered in the threat assessment. In the threat assessment, emergencies involving a combination of a nuclear or radiological emergency and a conventional emergency such as an earthquake shall be considered."*
(2)	**BASIS: GS-R-2 Para. 3.17 states that** *"In a threat assessment, facilities, sources, practices, on-site areas, off-site areas and locations shall be identified for which a nuclear or radiological emergency could warrant: (a) Precautionary urgent protective action to prevent severe deterministic health effects by keeping doses below those for which intervention would be expected to be undertaken under any circumstances (To include events with a very low estimated probability of occurrence)."*
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.**

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Establishing emergency management and operations

Regulatory requirements are in place to address the need for the prompt transition from normal operation to emergency operation command and control. Specifically, the Government Order of 7 February 2012 on BNIs requires the operator to put in place a permanent organization with designated staff that can recognize abnormal situations and trigger onsite emergency response plans and immediate actions. In addition, the order requires that a sufficient number of trained and qualified staff be available at all times to execute these response plan actions.

ASN's regulatory approach for verification of licensee's emergency management effectiveness includes a formal review of the onsite emergency plan as described earlier. All NPP emergency plans have been updated as of Nov 2014.

Identifying, notifying and activating

Regulations contain clear requirements for the operating organizations to notify, "without delay", and provide information to the offsite authorities. This is interpreted by ASN and the operating organizations to mean that this is the first action to take.

There is also no formalized system for classifying emergencies, in the sense that it is described in GS-R-2. There is a graded approach to emergency response: from emergency operating procedures (APE) to activation of the onsite plan (PUI), at which point offsite authorities are notified. The offsite authorities then decide to activate or not the offsite plan (PPI). If the event is a fast-kinetic event, the PPI is triggered in reflex mode, at which point immediate sheltering of

the immediate vicinity of the NPP can be initiated directly by the operator. A general definition of what constitutes an emergency is provided in the public health code but there is no requirement for the operator to develop operational criteria to trigger emergency (although, in practice, NPPs have defined plant parameters to trigger the emergency plan). This arrangement is not fully consistent with GS-R-2. The need to define triggers based on plant parameters is addressed in a draft regulation.

A draft ASN regulation [Décision n° 2013-DC-00XX] clearly states the requirement for the operating organization to reach an agreement with offsite authorities on the notification and interaction protocols.

There is a government order requiring a license issued by the prefect to operate a scrap metal facility. This includes the requirement for gate monitors.

Taking mitigatory actions

Several BNIs rely on outside services for support during an emergency. The 7 February government order requires that operating organizations establish formal agreements (conventions) with external services expected to provide assistance during an emergency. These agreements must be tested in exercises and are checked during inspections.

Taking urgent protective action and emergency planning zones

Intervention levels contained in the inter-ministerial directive of 7th April 2005 are fully consistent with GS-R-2. However, they are not consistent with the latest guidance (GSG-2) and will no longer be consistent with the revised GS-R-2 (GSR Part 7) when it is published. When the revised GS-R-2 is published, it would reasonable to review the question of intervention levels and determine what actions, if any, should be taken.

The requirements for the operating organizations to support offsite authorities in the implementation of offsite protective actions is part of the coordinating agreements that must be established between them, as clearly described in the existing regulations and legal texts related to EPR. There are provisions in both onsite and offsite plans to recognize fast developing accidents and accordingly to implement response actions in a precautionary or reflex manner.

A ministerial order issued by the ministry of interior and ASN requires that operating organizations put in place a process to ensure 100% availability of stable iodine to the affected public during an emergency. A working group led by ASN is defining a national strategy in that respect.

Providing information and issuing instructions

The public health code establishes the requirement for the operator of a BNI to inform the public living nearby of the need to take protective actions in the case of a fast-kinetic event. This is part of a reflex strategy carried out with the agreement of offsite authorities. Several organizations have a role, indeed an obligation, in public information during an emergency, including the ASN, the prefect and the operating organization. Regulations in this respect are, as mentioned before, well-coordinated and rely on the principle that each organization must confine statements to their respective area of responsibility. The draft regulation n° 2013-DC-00XX for BNIs contains a clear statement to this effect, which is consistent with the national strategy on public information. This approach is fully consistent with GS-R-2. The ability of the operating organizations to perform public communications is verified through inspections of procedures and evaluation of exercises.

ASN plays a major role in the provision of information to the public during the preparedness phase around BNIs, as part of the local public communication committees, composed of local representatives from various organizations (including interest groups), partly financed by ASN.

Protecting emergency workers

The public health code and the labour code address the need to protect emergency workers. Two types of emergency workers are considered in that context: group 1 emergency workers who may have to respond at the site, including site personnel and offsite emergency service personnel, and group 2 emergency workers, who are expected to work only offsite during an emergency. The dose limits that apply to both are not the same (100 mSv for group 1 and 10 mSv for group 2). As a result of this regulation, group 1 emergency workers receive significant training and frequently participate in exercises. Furthermore, this regulatory requirement ensures that all emergency workers at the site during an emergency, including plant personnel and offsite emergency services, are managed in a harmonized way in terms of radiation protection. This is identified as a Good Practice and is addressed in section 11.2.

Assessing the initial phase

There are no clear requirements on the assessment of the initial phase of an emergency. In practice, for BNI, the assessment is based on plant parameters for the reflex phase and on dose projections thereafter. IAEA safety standards [GS-G-2.1, para 4.27] discourage overreliance on computer models for the early assessment. This aspect is covered under the subsection on "Identifying, notifying and activating". The current approach could be completed to be more consistent with IAEA safety standards.

Managing the medical response

The need for the operating organizations to make arrangements for the protection of plant personnel and their medical treatment in designated hospitals is clearly stated in the EPR legal framework. The order of 22nd February 2002 clearly assigns the responsibility to IRSN for proposing medical measures in the case of an accident involving radioactive sources. There is a new government order that designates EdF as the resource for managing contaminated people that are non-critical victims of a contamination accident.

Other activities in emergency preparedness

The psychological care of persons affected by a radiation emergency are in part addressed in a government circular (DGSNR/DHOS/DDSC No. 2005/1390 of 23rd December 2005, for practices not requiring emergency plans) and in regulations (decisions) of 26 June 2012 adopted in response to the stress tests. This aspect is not currently addressed in the draft regulation on the contents of emergency plans, discussed in the next subsection on plans and procedures.

A committee led by ASN and composed of a wide array of stakeholders, including interest groups, has developed and published, in 2012, a strategic guide on post-accident transition and recovery. This guide is extensive and represents a consensus between all organizations involved. It is integrated with the national strategic plan for managing nuclear emergencies. Reference contamination levels are consistent with the EURATOM directive. Work on this subject is on-going. The leadership shown by ASN in this area, the level of development of this guidance, the integration with the national framework and the collaborative involvement of stakeholders and interest groups in the publication of the document are considered a good practice.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The regulatory requirement for an emergency classification system is not consistent with the concept described in GS-R-2.*	
(1)	**BASIS: GS-R-2 Para. 4.19 states that** *"The operator of a facility or practice in threat category I, II, III or IV shall make arrangements for the prompt identification of an actual or potential nuclear or radiological emergency and determination of the appropriate level of response. This shall include a system for classifying all potential nuclear and radiological emergencies that warrant an emergency intervention to protect workers and the public, in accordance with international standards, which covers emergencies of the following types at facilities: general emergency. site area emergency; alerts."*
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.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is a well-developed post-accident strategy, published in 2012, and representing a consensus between many organizations, including environmental groups, and three neighbouring countries.*	
(1)	**BASIS: GS-R-2 Para. 4.19 states that** *"The transition from the emergency phase to long term recovery operations and the resumption of normal social and economic activity shall be planned and made in an orderly manner and in accordance with international standards and guidance"*
GP5	**Good practice: The post-accident management guidelines have been developed, under the leadership of the ASN, and are the result of an extensive concerted dialogue between many different interested stakeholders and neighbouring countries. Work is under way to include as part of this guidance accidents with protracted releases and impacts beyond the emergency planning zones.**

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

In general, it was noted that some regulatory requirements are general and there is no detailed regulatory guidance on each of the aspects discussed below. Draft regulations and regulatory guides, in the process of being finalized and issued, address this issue directly. However, even in the absence of detailed regulations and regulatory guides, it was noted that operating organizations have in place EPR arrangements that meet most of the requirements addressed in this section, except where noted.

Authority

Authorities for EPR are well defined at all levels, as discussed in the rest of this section.

Organization

Regulatory requirements for staffing of the emergency response organization are clearly defined in the government orders (title 2 of 7 February "Arrêté"), for BNI. Draft ASN regulation (Decision n° 2013-DC-00XX) contains very detailed requirements on the need for appropriate staffing and the basis for determining the adequacy of the training. During inspections, the availability of appropriately trained and exercised staff for the emergency organization of BNIs is systematically verified by ASN inspectors.

Coordination of emergency response

The requirements for coordination between onsite and offsite organizations are clearly defined in the Public Health Code for BNIs. In addition, draft ASN regulation (Decision n° 2013-DC-00XX) contains detailed requirements regarding the modalities of this coordination, including the need for agreements to be reached between the organizations involved. In fact, as noted above and based on the interviews and site visits performed during this mission, the coordination arrangements between operating organizations, offsite authorities and the ASN appear to be excellent and much appreciated by all stakeholders.

Plans and procedures

There is currently no regulatory requirement or guide on the contents of emergency plans for operating organizations. However, for NPPs, a detailed template has been developed and submitted to ASN for concurrence. This template is used by all NPP operating organizations to develop their emergency plans and arrangements, and by the ASN to review these plans (with the technical assistance of IRSN). The template is comprehensive and, with a few exceptions, addresses all relevant requirements contained in GS-R-2 that apply to operating organizations. There is also a template for non-NPP BNIs, which is used in the same manner. A draft regulation (Décision n° 2013-DC-00XX) is being developed; it will contain a comprehensive description of the expectation of the ASN for all BNI emergency plans. This will be supported by regulatory guidance, also in draft. The review of the draft regulation indicates that it is complete and includes all relevant elements of the IAEA requirements in EPR, with the following exceptions: consideration for severe accidents, quality assurance, coordination of site personnel evacuation with offsite authorities (including offsite contamination control of contaminated personnel when contamination is present at the site), emergency classification, criteria for declaring an emergency, and management of non-radiological care of workers and emergency workers at the facility.

According to GS-R-2 para. 3.9, "*In fulfilling its statutory obligations, the regulatory body… shall establish, promote or adopt regulations and guides [...] that are clear and unambiguous and which shall specify [...] the requirements for [...]emergency preparedness arrangements*". The ASN should finalize the development of the draft regulation and guide on the content of emergency plans, and include the missing elements identified above. This is addressed in a Suggestion contained in section 9.1.

BNI emergency plans are reviewed and need to be accepted by the ASN. Source users need to have an emergency plan but there is no regulatory requirement on the content of this plan. For transport activities, the consignor and the carrier need to have the capability to respond to emergencies. There is also a draft guide on the content of plans for transport emergencies. Emergency plans and procedures are verified during inspections.

Logistical support and facilities

There are regulatory requirements for BNI to establish emergency logistics and facilities, contained in the 7 February government order. There is no detailed regulation or regulatory guide on emergency logistics support and facilities. However, the draft regulation (Décision n° 2013-DC-00XX) contains detailed requirements.

Logistical support, equipment and emergency facilities are inspected in detail during EPR inspections. They are compared to what the onsite plan stipulates. There is a comprehensive checklist for the inspection of EPR equipment and facilities.

Training, drills and exercises

For BNI, the minimum frequency of exercises and the scope of exercises are clearly defined in the regulations. The performance of the onsite organization, including the interface with offsite authorities, is evaluated by the operating organization and the ASN reviews corrective action reports (retour d'experience) and monitors the completion of corrective actions during inspections. In addition, the ASN performs surprise exercises, which can last several hours, with specific objectives; operators are not warned and the exercise objectives, which determine its success, are not communicated until after the exercise. This is considered a good practice.

There is no comprehensive evaluation tool (grille d'évaluation) to assess the performance of licensees in emergency exercises. While it is recognized that not all exercises are a test of performance (some are for training, for example), current evaluations are based on compliance with emergency procedures. There is no rigorous integrated system evaluation. Several countries have emergency exercise evaluation tools and methodologies, which allow for a consistent and reproducible evaluation of exercises. This type of tool could further enhance the quality of ASN's evaluation of exercises.

Before fuel or significant quantities of nuclear or radioactive material is brought to site of BNIs, EPR arrangements must be operational. There is no regulatory requirement to demonstrate this through an exercise but, in practice, this is done. The emergency plans are submitted to IRSN for verification. The verification is done against design basis events, on the basis of the emergency plan template agreed to with ASN. There is also a detailed guide on how to interpret the template and carry out the evaluation.

There is one national exercise per year for transport, including some at border locations.

Quality assurance programme

There is a general requirement for the operating organizations to ensure that their emergency plans and arrangements be managed through the organization's quality management system. This aspect should be referred in the draft regulation on the contents of emergency plans.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ASN conducts unannounced emergency exercises of NPPs.*	
(1)	**BASIS: GS-R-2 Para. 3.9 states that** *"Exercise programmes shall be conducted [...]. The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body."*
GP6	**Good practice: The conduct of unannounced exercises at NPPs, evaluated against specific objectives is considered a good practice.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no systematic tool or methodology for performance-based evaluation of exercises.*	
(1)	**BASIS: GS-R-2 Para. 5.33 states that** *"The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body*
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.**

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

During an emergency, the ASN is responsible for advising the CIC and, possibly, the Prime Minister, on strategic issues, advising the offsite authorities (the prefect) on protective actions for the public, monitoring the affected facility to ensure that appropriate measures are taken to manage the accident and communications with the public on regulatory issues related to the emergency. It is clear, as demonstrated in the 28 November 2014 exercise and through review of operational and preparedness documents, that they have appropriate training programmes, exercises, personnel, tools, facilities, and coordination arrangements with other organizations, in particular with the IRSN, to effectively carry out that role. Noteworthy is the fact that an ASN representative is present in the prefecture operations centre to provide technical advice and support during the emergency. There is also evidence of excellent cooperation between the ASN and the offsite authorities during the preparedness phase, as well as with the operating organizations for the development of well-integrated emergency response arrangements. The ASN is also well integrated in the national system for preparedness and response to nuclear and radiological emergencies.

There are 10 national exercises per year, four of which include simulated media pressure. ASN's performance is evaluated through feedback received from the prefect, debriefs by participants using a general evaluation checklist and, occasionally, feedback from external experts from other regulatory organizations. The evaluation checklist could be improved to include a more systemic, systematic and performance-based approach to exercise evaluation, as it is used in many countries. This could improve the value of the evaluation and provide a sound basis for continuous improvement.

There is no current on-call system for core staff. This issue has been identified and is under examination by ASN. It was also noted by ASN that ensuring continued staffing during a protracted emergency is a challenge. Discussions are on-going within ASN and with regulatory organizations in other countries to identify possible solutions. This is addressed in the Fukushima section.

While the CIC has participated in some government-level exercises, ministerial participation is not always the case, and the prime minister has not participated in recent exercises. Yet, it is expected that, given the importance and visibility of the nuclear issue, and the potential political ramifications, as witnessed during the Fukushima Daiichi accident, the interface between senior ASN representatives and the ministers (minister of Interior) and the prime minister would be active during a nuclear emergency. It may therefore be important to include his level of government representatives in some exercises.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The participation of senior government and political officials in exercises is not frequent.*	
(1)	**BASIS: GS-R-2 Para. 5.33 states that** *"Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces [...at] the national level programmes [...] are tested at suitable intervals. These programmes shall include the participation in some exercises of as many as possible of the organizations concerned."*
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.**

10.5. SUMMARY

The regulatory framework on EPR in France is a mature framework that is based on a highly collaborative approach between regulatory authorities and licensees. In general, it is consistent with the IAEA safety standards. Some areas require improvements, in the context of a continuous improvement process. They include the need to: address severe accidents with uncontrolled releases in the threat/hazard assessment; establish a clear emergency classification system; examine the question of intervention levels; re-examine the use of dose projection for urgent decision-making, particularly in the very early phase of an emergency; promulgate the regulations and guides on the content of emergency plans; develop a systematic, system- and performance-based exercise evaluation tool; include all key interfaces at the government and political levels in some exercises. Three good practices were noted: the high level of coordination of regulatory organizations in EPR and integration of the nuclear emergency arrangements with conventional emergency planning; the practice of carrying out unannounced emergency exercises at NPPs; and the publication of a strategic document on the post-accident phase.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

Responsibilities

The regulatory framework for medical exposure is mainly covered by Public Health Code and several decrees, Ministerial orders, ASN decisions and guidelines. The responsibilities for healthcare and regulatory control of medical exposure are fragmented among many organizations, see figure 1. There are conventions in place between ASN and most of these organizations and ASN is in discussion with the Ministry of Higher Education and Research to establish cooperation. The IRRS-team could not confirm that all organizations had the necessary competence in radiation protection and safety to undertake their responsibilities effectively. The IRRS-team identified a number of areas where the regulation was not fully in line with the GSR Part 3. ASN should take this into account in their updating of the national regulation in the medical field, during their transposition of the new European Directive on Basic Safety Standards. The IRRS-team acknowledged that ASN had noted most of these issues in their self-assessment and included actions to address them in their Action Plan.

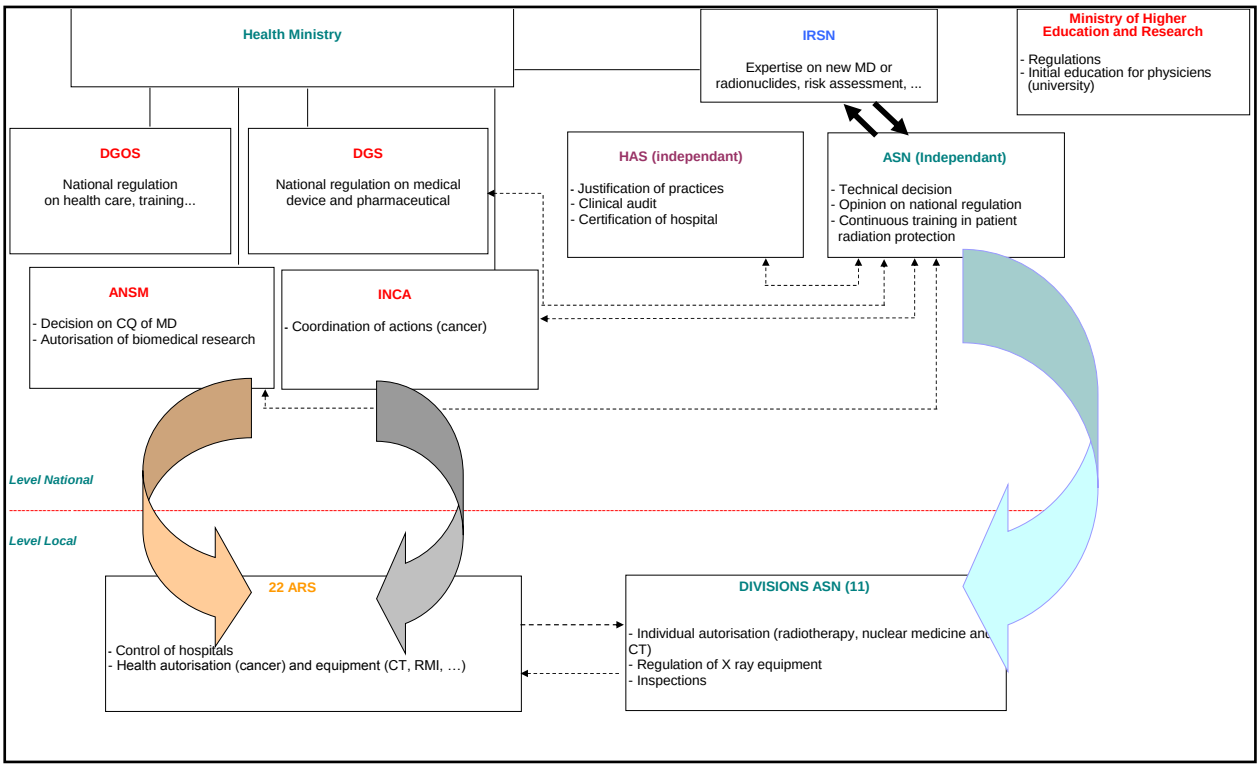

Figure 1 (by ASN)
Overview of the different parties with responsibilities within healthcare and regulatory control of medical exposure (MOH - Ministry of Health, DGOS - General Directorate of Healthcare Provision, DGS - General Directorate of Health, ANSM – Health and Safety of Health Products, INCA – National Cancer Institute, IRSN - Institute for Radiation Protection and Nuclear Safety, HAS – National Health Authority, ARS - Regional Health Agency)

The IRRS-team considers that the government should undertake a review of the regulatory framework for the control of medical exposure to ensure there are no gaps.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The regulatory control of medical exposure is fragmented among many organizations and the IRRS team could not confirm that they were appropriately coordinated to carry out the effective control of medical exposure. The IRRS team identified some gaps in the regulatory framework for the control of medical exposure.*	
(1)	**BASIS: GSR Part 1, Requirement 7, Para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as:* *(3) Applications of radiation in medicine, industry and research;* *This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience."*
(2)	**BASIS: GSR Part 1 Requirement 2 states that** *"The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated."*
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.**

In order to fulfil the responsibilities of the government to stipulate the necessary level of competence for persons involved in medical exposure, arrangements are in place for the provision of recognized educational programmes for health professionals. Ministerial orders define the qualifications required for persons to be responsible for practices within medical exposure (order of 30th November 2011), the training and duties of medical physicists (order of 6th of December 2011) and training programmes concerning the radiation protection of patients exposed to ionizing radiation (order of 18th May 2004). These training programmes are to be implemented by responsible training providers. Diplomas for the training courses on radiation protection of patients are not a requirement of ASNs licence and the IRRS-team observed during the site visit at Saint-Louis University Hospital that the necessary diplomas were not available for some of the health professionals. ASN is planning to make this training a requirement in the licensing procedure as already identified in its Action Plan. High patient and staff doses are reported for interventional procedures and the IRRS-team was informed that nurses, who are not trained in radiation protection, often operate the equipment due to lack of radiation technologists. The IRRS-team noted that ASN has identified a need to revise the training programme on patient radiation protection to make it more practical and based on skills and competence. ASN has also identified a need to make arrangements to assure that all personnel involved in medical exposure meet the requirements for training and education in radiation protection (especially for interventional radiology). The IRRS-team identified a need for arrangements to assure the appropriate education and training for all parties involved in medical exposure as recommended in Section 1.8, Chapter 1 (R3).

Justification

Justification is well covered in the PHC (R.1333-56 to R.1333-57) and is in good compliance with most of the requirements in GSR Part 3. HAS issues guides that cover generic justification of new practices involving medical exposure before they are adopted for general use in the medical sector, for example, the use of Cone Beam CT in dental practices. There is no formal procedure covering generic justification. INCA is responsible for evaluating the justification of screening programs and ANSM gives the authorizations for biomedical research based on a favourable opinion from an ethics committee (L. 1123-12, L. 1123-1). The IRRS Team could not establish if these parties have access to expertise in radiation protection and it noted that ASN is not involved in the regulatory control of the use of ionizing radiation in screening programs and biomedical research. Generic justification, justification of screening programmes and biomedical research together with the issues related to biomedical research identified in the report from the IRRS-mission in 2006 should also be covered in the review of the regulatory framework suggested above.

National referral criteria for medical exposure are developed by HAS with the support of professional bodies and ASN. These criteria are updated regularly, contain dose indicators and are also available on smart phone devices, but the IRRS-team was informed that the level of implementation among referring physicians is limited. The IRRS-team noted that ASN has included initiatives to further promote national training for referring physicians and to increase awareness and implementation of national referral guidelines in their Action Plan. ASN has made it mandatory to document individual justification in the radiological examination report (Ministerial order 22nd September 2006) and it seeks verification of this during its inspections.

Optimization

The PHC includes requirements for optimization, maintenance, quality assurance (QA), quality control (QC) and the involvement of medical physicists (R.1333-59 to R.1333-66, R.1333-59, R-1333-60, R.5212-25 to R.5212-35, order of 19th November 2004), but the IRRS-team identified that some of these issues were not fully in line with the requirements in GSR Part 3. Based on recent accidents in radiotherapy with detrimental outcomes for patients, ASN has increased its efforts in radiation protection by introducing requirements for quality assurance for radiotherapy (Resolution 1st July 2008). ASN inspections have identified some variations in the level of local implementation of this QA programme. The IRRS-team identified the importance to have similar QA programs controlled by ASN for nuclear medicine and radiology. The National Cancer Plan includes an action to introduce QA and training in medical imaging under the responsibility of ASN (action 12.7 in Plan Cancer 2014-2019). As a result of the 2009 IRRS Follow-up mission, ASN brought the shortage of medical physicists to the attention of the MOH and the availability has increased since then, but there is still an overall shortage of medical physicists. The IRRS-team was informed that ASN cannot confirm that medical physicists are involved in QA, dosimetry and QC in all medical practices. The legal requirement for the involvement of medical physicists is not linked to the complexity of the procedure and the associated radiation risk. An ASN guide provides recommendations for the minimum staffing level of medical physicists in medical imaging, but such guidelines are not provided for radiotherapy. Arrangements to ensure the appropriate involvement of medial physicists in all medical practices should be included in the review of the regulatory framework for medical exposure suggested above. DGS is responsible for the regulation of medical devices and ANSM issues criteria for the QC of medical equipment. These criteria cover the physical parameters to be measured, the corresponding acceptability criteria and the frequency of QC-measurements. The IRRS-team identified some areas for improvement with regard to QC; for example, QC of software is only covered in radiotherapy and there are no requirements to assure that the calibration of all

dosimeters used for patient dosimetry is traceable to a standard dosimetry laboratory. The introduction of QA programmes for nuclear medicine and radiology should take into account the QC of software and a traceable calibration of dosimeters used for patient dosimetry. Internal and external audits of QC for all equipment together with external dosimetric audits in radiotherapy are mandatory.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *QA in medical exposure is not fully implemented, gaps in the QC criteria were identified and there were no requirements for traceable calibrations of dosimeters used for patient dosimetry and calibration of sources.*	
(1)	**BASIS: GSR Part 3 Para. 3.170 states that** *"The registrants and licensees, in applying the requirements of these Standards in respect of management systems, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate…."*
(2)	**BASIS: GSR Part 3 para. 3.171 states that** *"Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility: (a) … (iv) After any installation of new software or modification of existing software that could affect protection and safety of patients."*
(3)	**BASIS: GSR Part 3 para 3. 3.167 states that:** *"(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory."*
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.**

National diagnostic reference levels (DRLs) are established for nuclear medicine and radiology (PHC R.1333-68, Ministerial order 24th October 2011) but there is no requirement for establishing DRLs for interventional radiology. IRSN collects and analyses patient doses submitted from the facilities and the results are published in reports. The medical expert group attached to ASN, (GPMED) makes recommendations for new or revised DRLs based on proposals from IRSN and a Ministerial order is prepared by ASN. There are requirements for the licensee to perform local review of the practice if the patient doses exceed the national DRLs, but there is no such requirement if the patient doses fall substantially below the national DRLs. The image quality has to be taken into account in QA programs for medical imaging when they are introduced. To allow for the establishment of national DRLs to be based on wide scale surveys, all medical facilities are obliged to submit doses for two examinations each year to IRSN. The IRRS-team was informed that the fulfilment of this requirement was limited for diagnostic radiology. Requirements for dose constraints for carers and comforters and for volunteers participating in biomedical research are provided in the PHC (R.1333-65), but the IRRS-team

was informed that the use of dose constraints was not fully implemented and not included in ASN inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no requirements to establish DRLs for interventional radiology and no requirement to perform a review if the patient doses fall substantially below the national DRLs.*	
(1)	**BASIS: GSR Part 3 Para. 3.148 states that** *"The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances."*
(2)	**BASIS: GSR Part 3 para. 3.169 states that** *"Registrants and licensees shall ensure that:* *(a) Local assessments, on the basis of the measurements required in para. 3.168, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established (para. 3.148).* *(b) A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure:* *(ii) Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.*
R14	**Recommendation: ASN should establish DRLs for interventional radiology, and assure for local review of practice if patient doses fall substantially below national DRLs.**

Pregnant and breast feeding women and release of patients

Radiation protection of pregnant and breast feeding women are covered in the PHC and special attention is given to the justification and optimization process (R.1333-63, R.1333-70 to R.133372) and are covered by ASN inspections. Release of patient following radionuclide therapy is covered in PHC (R.1333-64) and the information provided to the patient is standardized (Ministerial order 21st January 2004). The High Council of Public Health (HCSP) has published release criteria for patients and a dose constraint of 0.3 mSv is proposed. The IRRS-team identified some minor gaps in the regulation compared to GSR Part 3 with regard to pregnant and breast feeding women and release of patients. These gaps should be analysed in their process for updating national regulations as suggested in Chapter 9.

Unintended medical exposures

All health facilities are obliged to have a risk management system to prevent adverse events (L.6111-2, HPST Law), which is inspected by ASN. All incidents and accidents related to medical exposure, medical equipment and patients must be notified respectively to ASN, ANSM and ARS. The requirements regarding notification of incidents or accidents in the field of radiation protection to ASN are set out in PHC (L.1333-3). Two ASN guides are available and a scale for classification of the events seriousness (ASN-SFRO scale) is established for radiotherapy. Cooperation on exchange of information and follow up of adverse events are established between responsible parties. Events must be analysed and an ASN guide provides a template that defines a two-month timeframe to conduct this analysis. ASN, together with other organisations (ARS, ANMS, IRSN, etc.), follow up all notified events. ASN publishes quarterly newsletters on unintended events and accidents and the more severe events are published on the ASN website. ASN has established a notification system for all events. Notification forms are available on the ASN website and submission of events on medical exposure will go online in 2015. Notification criteria and the corresponding timeframe are not mandatory and are not fully harmonized with the criteria given in GSR Part 3. The IRRS-team acknowledged the efforts of ASN to cooperate with other authorities; to involve stakeholders in the lessons learned from notified events; to regularly publish information about events on their website and to actively feed this information back to the users (see Good Practice in Chapter 3). ASN is also highly involved in European and international initiatives to reduce unintended medical exposure.

Review and records

Requirements for continuous assessment of clinical practices involving exposure to ionizing radiation are given in the PHC (R.1333-73). A system for periodic radiological review has been established by HAS. They provide a guide presenting different programmes allowing a critical review of the practical application of the radiation protection principles of justification and optimization in medical radiation facilities. ASN verify if this review has been carried out during their inspections. This program was implemented in 2014. Today only internal reviews are performed, but ASN is promoting the need to establish a system for external audits. The PHC provides the necessary requirements for record keeping with the exception of the records of assessments and reviews against DRLs and reports on investigations of unintended and accidental medical exposure. These gaps should be analysed in the process for updating national regulations.

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and regulatory framework

The national regulatory framework for occupational exposure is covered mainly by the Labour Code (CoL), by the Code of Public Health (CoPH), and by the books I and V of the Code on Environment (CoE). The French Agency for Nuclear Safety (ASN) is in charge of controlling the compliance with the requirements provided in these codes. The global structure is based on laws edicted by the Parliament, on decrees and orders at the level of the Government (advisory input from ASN), on technical regulatory decisions produced by ASN and being validated by Ministerial Orders on technical prescriptions and guides both produced by ASN itself. During the last ten years, a lot of regulatory resolutions have been adopted providing detailed information about the dispositions of the Codes, in particular on Labour Code. In order to facilitate the implementation of the regulations by the end-users, DGT envisages the production of guidance material summarizing the main issues to be complied with depending upon the end-users activity. A convention whose revision has recently been done is waiting for final approval by the

direction of DGT and of ASN This convention defines, among other, the areas and the type of co-operation between the "Direction Générale du Travail" (DGT) and ASN.

ASN benefits from the support of the Institut de Radioprotection et de Sûreté Nucléaire (IRSN). IRSN's missions are defined by Decree. As such, IRSN is not a Technical Service Provider (TSO) but provides contribution to ASN through advices on technical areas. IRSN is also in charge of the management of the "Système d'Information et de Surveillance des Expositions aux Rayonnements Ionisants" (SISERI) which is the national dose records register. SISERI main roles are described in the CoL R.4451-125,-128 and by the Order on July 17,2013. Objectives are also to provide assistance to the Government on policy issues and to make data available for epidemiology studies. ASN is not associated with the management of SISERI, nor on management issue, nor on financial issue.

The expert had the opportunity to meet a representative of the DGT and discussions were held on several items related to the status of the working groups on dosimetry, on the implementation of the zonage approach regarding supervised and controlled areas, on the co-operation for the inspections and on the potential improvement of the transmission of dose records, in particular for situations requiring the implementation of protective actions in case of internal contamination. Although the general position of the Ministry of Labour is to maintain the actual regulatory framework, improvements to consider more flexibility are not excluded. For example, it has to be mentioned that the role of the Labour physicians is still a key point as far as the transmission of dose data records is concerned. The DGT is aware of the problem mainly due to the confidentiality of the internal dose records and is open for examining some situations where – under well and still to be defined – conditions, information could be made available in order to allow the set-up of adequate protection measures when needed. Nevertheless, close co-operation between DGT and ASN is well established and, for example, response to questions arising from professionals or from the public on radiation protection issues or on nuclear risks are before answering validated by both parties and ASN is managing a data base collecting these information.

Workers' radiation protection is considered for all kind of exposures: occupational exposure, existing exposure situations (workplaces, NORM industries, radon exposure and aircrew exposure for example) and workers exposure involved in emergency situations. The three basic principles on radiation protection are present as well as the limits for the workers. Special arrangements are also described for pregnant women, for young people and dosimetry of crew members is also considered. Operational dosimetry is mandatory in controlled areas.

The regulations establish clearly the responsibilities of the employer (the "user") and of the employer of the external company (the "provider") in order to ensure compliance with the regulations also for outside workers operating in installations where ionizing radiations are used and/or produced.

ASN requires for each activity giving rise to potential exposure to ionising radiations to be either authorized either notified. Inspections are carried out by ASN and comprise planned and unplanned inspections, global and thematic inspections. For nuclear power plants, in addition to the radiation protection area, ASN inspectors act as inspector for the Ministry of Labour covering all aspects related to safety on the workplaces.

The approach developed by the ASN regarding the regulatory provisions for the emergency workers has to be stressed on. The regulations provide for a clear definition of the categories of workers involved in emergency situations, of the dose limits and reference levels to be applied, for dose records keeping, for the training to be given as well as on the availability of protective equipment and the dosimetry devices (CoPH : L.1333-6, R.1333-83, R.1333-84, R.1333-86; CoL

: R.4451-1). Distinction is made between three levels : firstly, the workers belonging to the facility where the emergency is taking place, secondly the so-called group 1 workers which have been identified, trained and which will act in the installation together with workers of the previous category and thirdly, the so-called group 2 which is composed by individuals belonging for example to the police and to any other civil intervention team. Actions of this last group are only allowed in the neighbourhood of the concerned installation or plant.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team noted the approach developed by the ASN regarding the regulatory provisions for the emergency workers. Clear identification of the people, of the content of the training to be provided, monitoring requirements as well as dose limits to be complied with are part of the regulations. This will save time and increase efficiency on the site concerned, as well as at locations in the neighbourhood.*	
(1)	**BASIS: GSR Part 1, Requirement 8 states that** *"The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 3, Requirement 45 states that** *"The government shall establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers."*
GP7	**Good Practice: French regulations have set up clear regulatory provisions to describe the management of people in emergency situations.**

Authorization may be granted to employers, licensees under the condition that their demand addresses, among other, the provisions made concerning the establishment of a radiation protection programme. As far as the INB (Installations Nucléaires de Base, such a Nuclear Power Plants for example) are concerned, it seems that the existing regulations may lead to different interpretations. Indeed, as indicated in the CoPH (Art. L.1333-4), INB are subject to the dispositions of the previous law n°2006-086 on June 13,2006 which is now part of the CoE. For the Ministry of Labour, there should be no difference between all the workers exposed to ionizing radiations and the INB should also comply with the requirement.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Authorization may be granted to employers, licensees under the condition that their demand addresses, among other, the provisions made concerning the establishment of a radiation protection programme. There is still discrepancy between the understanding of this requirement by the ASN, DGT and by operators of basic nuclear installations.*	
(1)	**BASIS: GSR Part 1, Requirement 23 states that** *"Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."*
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.

General responsibilities of registrants, licensees and employers (PCR,RPO,RPE)

The implementation of the regulations is under the full responsibility of the employers as prescribed by the Code of Labour (CoL : L.4121-1 to L4121-5). This means that employers have:

- to perform, and to review if needed, the risk assessment in their facility and to use the results for identifying supervised and controlled areas and defining for the rules for access (CoL: R.4451-112) and for emergency situations;
- to nominate the competent person for radiation protection (CoL: R.4451-103) and to provide him all means required for performing his tasks (CoL R4451-114);
- to provide protective equipment (CoL : R.4321-1 to R.4321-4) and personal exposure monitoring devices(CoL : R.4451-30; R.4451-62 to R.4451-66);
- to implement the radiological monitoring and recording of occupational exposures (reference and operational dosimetry as well as workplaces dosimetry) (CoL R.4451-61 to R.4451-67)
- to make arrangements for the specific information and the practical and appropriate
- training in radiation protection (CoL : R.4323-1 to R.4323-5; R4451-9,-47,-51,-52),
- to make arrangements for ensuring the implementation of the health surveillance;
- to give appropriate information about the findings of the workplace monitoring programme to workers and their representatives.

The CoL make also provisions concerning regulatory obligations for external contractors (L.4451-1,-2; L.4511-1; L.4111-6; L.4121-1,-2) and the need for coordination on prevention measures between them and the “user” (L. 4522-1, -2).

Responsibilities of employers, licensees and employers regarding sources, ionizing radiation producing devices, protective equipment and measuring devices (individual and ambient dosimetry) and the controls of them are described in the CoL : R.4451-29 to 34.

General Responsibilities of workers

Workers responsibilities are described in the Code of Labour which states that the workers have to perform their tasks by taking care for their own safety as well as for the safety of the other persons concerned by their tasks (CoL: L4122-1, R4451-9,-52). Moreover, these responsibilities are also applicable for situations where workers are exposed to the risk of ionizing radiation in emergency situations, existing exposure situations and in workplace where natural radionuclides, non-used for their nuclear characteristics, are present and potentially giving rise to exposure above the background at a level where potential health effects for the workers are not excluded (CoL : L-4451-1,-2,-4,-9).

Requirements for radiation protection programmes

Beside the observations made in the section “Legal and regulatory framework” and as an important tool for the implementation of a radiation protection program, the optimization principle is required by the French regulations. Nevertheless, for reasons related to general legal framework, references to the implementation of dose constraints are limited in the regulations. There is also no guidance at the present time on how to implement this principle in practice.

The expert had the opportunity for taking part to an inspection in some installations on the site of La Hague. The main purpose of the inspection was to check the level of compliance with radiation protection regulations. Inspectors from ASN with technical support from IRSN conducted the inspection. The level of commitment of the operators concerning the implementation of the ALARA principle has to be stressed on. All the operations are covered by a DMIR ("Dossier d'Intervention en Milieu Radioactif") which establishes a detailed prognosis of the doses for the workers for all the operations and is managed in a dynamic way as the review of the dose constraints is systematically performed when work conditions are modified. Considering the operations done in the visited installations (dismantling and/or setting of new equipment), this approach results in a significant reduction of the collective dose as well as the maximal individual dose of the workers. Value of dose constraints are defined at the local level and ASN inspectors check compliance during the inspection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A full implementation of the optimization principle is at this moment not yet achieved as there is no national regulatory guidance on how to implement the optimization principle. Some operators are aware about the added value of the optimization principle and are developing strategies aimed at implementing the ALARA principle .*	
(1)	**BASIS: GSR Part 3, Requirement 11 states that** *"The government or regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized"*
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.**

Monitoring programmes and technical services

Agreement of dosimetry service providers is granted in a two steps process : accreditation by COFRAC (COmité FRançais d'ACcréditation) and final agreement by ASN. A the present time, they are 10 services providers for external dosimetry and 10 services providers for internal dosimetry. The agreement is provided for a period of 5 years and ASN applied a proactive approach for the renewal of the agreement as a reminder to the agreement holders is sent 6 months before the end of the agreement. Concerning radon, the first agreement is provided for a period of one year and, in case of renewal, this period is extended to 5 years.

In 2013, 352 082 workers were concerned by the monitoring of occupational exposure:

- 63.3 % in medical and veterinaries activities,
- 19.5 % in nuclear power plants and transport,
- 9.5 % in non-nuclear industry,
- 3.7 % in research and training,
- 4.7 % in various areas (vets, logistical units, …)

The total collective dose amounts 68,47 man.Sv and the mean annual effective dose for all monitored workers is 0,19 mSv. There is no extremity dose higher than 500 mSv and they are 9 workers whose annual effective dose was above 20 mSv. The number of workers having received a committed dose above 1 mSv is 18 for the year 2013.

Through a secured access process to SISERI, Labour Physicians have full access to all dose data and in particular to the data related to internal dose. These data are considered in the French regulatory context as confidential personal data. Inspectors of ASN may also get access to dose data (only operational and effective doses). There is no direct access to them and inspectors needs to introduce a demand at IRSN for getting them. The report of the first IRRS mission in 2006 already pointed out in its action R6 that "ASN should initiate and make arrangements to improve the timely reporting of occupational radiation exposure for oversight and analysis of radiation protection practices". The 2009 follow-up mission closed this action as ASN provided evidence about a prompt information to be sent to ASN when worker exposure should be beyond regulatory limits. Other situations were not considered.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In order to improve the control and the implementation of protection measures for workers, availability of dose data for ASN and, when appropriate for the CPR, should not be limited to overexposure situations.*	
(1)	**BASIS: GSR-Part 3, Requirement 13 states that** *"The government shall make provision, where necessary, for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment."*
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).**

As pointed out by the ASN in the preliminary assessment (Action 89 in the ASN Action Plan), an inspection programme of workplace concerned by a radon risk, needs to be launched. At the present time, the approval of service providers for radon measurements is set up as well as the implementation of inspection programme for these approved services. The regulations require radon measurements to be performed in the workplaces but between 2010 and 2013, only 65 measurements have been made (IRSN Source). The radon prone areas have been identified through a general country survey and are also kept to manage the radon in public buildings.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although the legislation requires radon measurements to be done in the workplace, there is poor compliance.*	
(1)	**BASIS: GSR Part 1, Requirement 9 states that** *"The government shall establish an effective system for protective actions to reduce undue radiation risksassociated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization."*
(2)	**BASIS: GSR Part 3, Requirement 47 states that** *"The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection."*
(3)	**BASIS: GSR Part 3, Requirement 52 states that** *"The regulatory body shall establish and enforce requirements for the protection of workers in existing exposure situations."*
S26	**Suggestion: ASN should take advantage of the launch of the national inspection program for radon in the workplace to improve compliance.**

Radiation Protection Experts/Officers

As prescribed by the CoL: R.4451-103, employers have to nominate "une Personne Compétente en Radioprotection" (PCR) for activities which can lead to risks from ionising radiations. Considering that there was a need for stressing on the practical part of the training, French regulations have been completed by the Ministerial Order on December 6, 2013 describing the ways for providing the training and the certification of the PCR. This Order considers also a graded approach for the definition of the objectives of the training with regards to the nature and the importance of the radiological risks and by addressing the principle of the certification of a training service provider instead of the principle of certified trainer. At the present time, PCR networks exist in many regions of France and CORPAR - which states for "Coordination des Réseaux de Personnes Compétentes en radioprotection et des Acteurs de la Radioprotection" - acts as coordinator. They are 15 networks for a total of 1500 CPR. Other PCR to a total of 4500 are also present in professional networks such as for EDF, for veterinaries and for CEA. One action undertaken by CORPAR is to develop a new approach for the training related to the renewal of the certificate. Instead of a training provided in "one shot" (a few hours or days), the certificate could be renewed based on a continuous process under guidance from a certified company. ASN is strongly associated to the CORPAR activities by providing logistic support.

The role and the competence of the CPR has been acknowledged and is dealt with in Module 1.

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

Control or Radioactive Discharges and Materials for Clearance

Both the Code of Environment, which regulates the activities of BNIs and ICEPs, and the Public Health Code, which regulates the activities of the rest of installations using radioactive sources (including medical services), require from the users they regulate to obtain an authorization for releasing radioactive materials to the environment.

For the case of BNIs and ICEPs, the authorized discharge limits values are explicitly included in the issued authorization. Other operators that use unsealed sources, including nuclear medicine services, must store produced waste contaminated with short lived radionuclides (less than 100 days) until decay, according to a procedure described in Title III of ASN Resolution 2008-DC-0095 of 29th of January 2008. For waste containing radionuclides with half-lives longer than 100 days, these facilities should apply for a discharge authorization, and on the basis of the mentioned before Resolution and the PHC the ASN establishes the conditions for discharges, requiring from the licensee to implement a monitoring program and informing periodically the concerned local residents or municipalities on the results of this program.

The basis for establishing authorized release limits values for the case of BNIs and ICEPs is a radiological impact assessment, as required by the regulations. However, the concept of dose constraint is not applied when establishing these release limits. Instead of this, the approach of Best Available Techniques (BAT) is used for establishing the release limits values. In this context, the concept of BAT is applied as defined in the Directive 2010/75/EU of the European Parliament and of the Council. According to this approach, the values of authorized discharge limits are set on the assumption that in controlling the effluent emissions the BAT are used. At the same time regulations require the operators to review every ten years the performance of technologies in use for limiting the releases and, taking into account the evolution of BAT and the economic feasibility of their implementation, upgrading these technologies in order to reduce further the amount of radioactive discharges. When judging on the adequacy of obtained results, evaluated dose evaluations are compared with the limit for the public of 1 mSv/y and there is no any quantitative criterion for determining the acceptability of calculated dose values. For some installations, in particular the BNIs, IRSN advises the ASN on the adequacy of the application of BAT approach for limiting radioactive releases to the environment. Nevertheless, considering that the application of BAT approach to the limitation of discharges has allowed achieving dose values to exposed population in the order of some μSv/y and lower, levels which are significantly below the order of usually accepted in practice dose constraints (tens to hundreds of μSv/y), it is possible to conclude that this approach can be considered a valid approach for optimization in limiting the radioactive releases to the environment.

Regarding the application of clearance concept, French regulations establish that, with the exception of cases mentioned earlier of facilities managing materials contaminated with radionuclides of less than 100 days half-life, the rest of contaminated materials are considered as radioactive waste. In fact, although the regulations do not establish explicit and nuclide specific clearance levels, this approach is equivalent to “clearance level zero” for all radionuclides, which can be considered in line with the IAEA standards (GSR Part 3, requirement 8, paragraph 3.12). With regard to the application of clearance levels as a way for reducing the generation of waste (as mentioned in GSR Part 5 para. 4.9), the French approach is to reduce waste at generation by the application of adequate procedures for reuse, recycling, characterization, sorting, treatment and packaging.

Environmental monitoring for Public Radiation Protection

ASN Resolution 2013-DC-0360 of 16th of July 2013 establishes in its Title III the requirements for environmental monitoring, detailing the minimal extent of the environmental monitoring programs to be carried out by the BNIs as part of their integrated management system. For the rest of facilities, the general requirements concerning environmental monitoring have been established in ASN Resolution 2008-DC-0095 of 29th of January 2008. These regulations require the licensees to implement a monitoring program, which must be proposed when applying for the authorization and which is included as a condition in the licence issued.

In addition to these requirements, in France a wide program for monitoring of radiation levels in environmental objects is in place. IRSN has as part of its duties the responsibility for ensuring the radiological surveillance of national territory. This is accomplished through the collection in all compartments of the environment (air, water, soils, foodstuffs, etc.) and measurement of more than 25000 samples per year and the maintenance of nationwide monitoring networks which watch over the radiation levels in air, water bodies, ambient gamma dose rates.

For BNIs, operators are required to collect a specified number of samples from the discharges on a regular basis and to forward them to an independent laboratory for analysis. The results of these analyses should be sent to ASN as a demonstration on the accuracy of results of the operators monitoring programs. The adequacy of monitoring results is verified by ASN also through direct measurements carried out by IRSN in its name or by ASN inspectors during inspections, as well as through the collection of samples which are sent for being measured to laboratories with recognized by the ASN competence for carrying out measurements needed.

French regulations require licensees to report the results of their monitoring programs and to make them publicly available. At the same time the results of monitoring programs carried out by the IRSN, together with the measurement results of the most relevant nuclear facilities are published periodically in an IRSN report. A summary of these results and an evaluation of doses received by the population living near the main French nuclear installations are provided also as part of the ASN annual report. Copies of these annual reports can be freely accessed through the web, in the sites of the IRSN and ASN. Additionally, information on monitoring can be obtained in the website of the National Environment Network (http://www.mesure-radioactivite.fr/public/).

11.4. SUMMARY

Regulatory control of medical exposure is well covered in the PHC but not fully in line with the GSR Part 3. The regulatory control of medical exposure is fragmented among many organizations and the IRRS-team identified a need for a review to identify if there is any gaps in the framework and that all relevant parties (organizations, licensee and registrants, personnel) have the necessary competence to undertake their responsibilities. Recommendations on implementation of QA in all medical practices, improvements in the QC of radiological equipment, traceable calibration of patient dosimetry and sources, and establishment for diagnostic reference levels in interventional radiology is areas where improvements should still be done. Good practice related to the transparency and stakeholder involvement in the lessons learned from notified events is recognized.

Regulations on occupational exposures are almost in full compliance with the Standards. Recommendations on access to dose records data, suggestions for additional guidance on the implementation of the optimization principle and of radon measurements in workplaces are examples of areas where improvements should still be done. Good practices related to the provisions for emergency workers as well as to the ASN support to PCR networks are recognized.

Existing regulations require from the users to obtain an authorization for discharges. Authorizations establish the conditions for releases and discharge limits. The application of BAT approach for optimization of discharges has allowed achieving significantly low dose values to the public. Clearance is applied for materials contaminated with radionuclides of less than 100 days half-life, whereas for the rest of radionuclides contaminated materials are considered as waste, which is equivalent to a practical "clearance level zero". French regulations establish requirements for the implementation of environmental monitoring programs for facilities that release radioactive materials to the environment. A system for verifying the validity of the monitoring results exists and a nationwide environmental monitoring program is carried out by IRSN. Results of monitoring programs are made publicly available through different publications and web sites.

12. INTERFACE WITH NUCLEAR SECURITY

The organizational structure of authorities involved in regulation and control of security matters in France is as follows:

The General Secretariat for Defence and Security (SGDSN) is in charge of defining the policy in different areas related to defence and security such as: policy for security of critical infrastructures, policy for elaboration of a design basis threat, policy for protection of sensitive information and cyber security. The SGDSN is also in charge of planning the contingency and emergency response to a nuclear security event that would occur outside a nuclear facility and is in charge of planning the radiological emergency response to a nuclear security event that would lead to radiological consequences in a nuclear facility.

The Ministry of Ecology, Sustainable Development and Energy has the responsibility for ensuring the security of nuclear facilities according to the policy defined by the SGDSN and in line with the dedicated legislation and regulation on the protection of nuclear material their facilities and their transport. The Department for nuclear security of the ministry is in charge of issuing the design basis threat (DBT) based on the threat assessment provided by the SGDSN, issuing regulation on nuclear security in relation with interested ministries and other State related organizations, licensing nuclear activities from a nuclear security perspective, controlling the licenses and whenever necessary taking appropriate sanctions. The Department for Nuclear Security uses expertise from its technical support organization (IRSN).

The Ministry of Interior is responsible for the State's armed response in case of a security event and of intelligence gathering as regard the threat.

The Ministry of Foreign Affairs is consulted whenever export and import of nuclear material are concerned.

The Ministry of Justice would be responsible for the penal response and pursuits.

The Ministry of Defence is responsible for airspace security.

12.1. LEGAL BASIS

There is neither mention nor reference to security regulations applicable to security issues included in the self-assessment. According to answers provided by ASN representatives there is a law in force developed through fifteen decrees all of them devoted to regulated security of nuclear facilities.

All the mentioned provisions and regulation are applicable exclusively to nuclear facilities and transport of nuclear materials. Neither regulation nor authority structure in charge of security of radioactive sources has been established. There is a project of law sent to Parliament long time ago that if once approved and implemented will solve this situation. It identifies ASN as the responsible authority both for authorization and control and identifies a need for co-operation and coordination both with Ministry of Ecology and the SGDSN. Approval of this regulation is a key for complying with international recommendations (IAEA Code of Conduct) and with the commitments taken by France.

For BNI and ICPE facilities ASN plays an active role to assure that security measures are implemented in such a way that they don't compromise safety. Specifically all regulations on security of these facilities are subjected to advisory report by ASN. However the Environment Code does not include any provision allocating security responsibilities to ASN.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *For BNI and ICPE facilities ASN plays an active role to assure that security measures are implemented in such a way that they don't compromise safety. However there is no legal basis for these activities as security responsibilities have not been allocated to ASN.* *There is no legislation on security of radioactive sources in France, so neither authority nor regulatory body responsible for this issue has been identified. Consequently activities required by international regulations (mainly IAEA Code of Conduct) are not being carried out.*	
(1)	**BASIS: GSR Part 1, Para. 2.39 states that** *"Specific responsibilities within the governmental and legal framework shall include:* *(a) Assessment of the configuration of facilities and activities for the optimization of safety, with factors relating to nuclear security and to the system of accounting for, and control of, nuclear material being taken into account;* (b) *Oversight and enforcement to maintain arrangements for safety, nuclear security and the system of accounting for, and control of, nuclear material;"*
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**

12.2. REGULATORY OVERSIGHT ACTIVITY

In relation to interfaces of safety and security two aspects were discussed during the interviews:

- Whether security requirements assure that all areas of the facilities and all SSC critical for safety area are adequately protected.
- Whether security measures in place at the facilities are going to prevent or make more difficult implementation of the mitigation or response actions in case of accident.

For the first aspect ASN made a specific advice on the project of law and on every decree project related to security of nuclear facilities released so far. However for specific facilities two separated processes for authorization and control take place, one considering safety aspects led by ASN and one considering security aspects led by the Department for Nuclear Security. No provisions for the assessment of the configuration of the facilities considering both aspects are taking place.

No action is being taken by ASN by inspection or assessment to assure that security measures in place do not prevent or difficult implementation of mitigation or response action.

There is a regulatory provision stating that ASN inspectors have the obligation to communicate to the inspectors from the Department for Nuclear Security any finding related to security observed during their inspections on safety issues. ASN inspectors have carried out some joint inspections on security and safety issues together with inspectors from Department for Nuclear

Security but this is very seldom. There is an ASN will to increase the number of these inspections.

ASN representatives explained that new ASN staff receives some generic training on security topics but no specific training about security of facilities and activities is included in the ASN training programme.

ASN does not have liaison agreements with law enforcement agencies to assure that they have adequate training on safety issues so that in case they have to carry out an intervention for security reasons safety provisions are respected.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *For BNI and ICPE facilities ASN does not carry out verifications through inspections or assessments to ensure that security measures in place do not impair actions for prevention or mitigation in case of accident.*	
(1)	**BASIS: GSR Part 1, Para. 2.39 states that** *"Specific responsibilities within the governmental and legal framework shall include:* *(c) Assessment of the configuration of facilities and activities for the optimization of safety, with factors relating to nuclear security and to the system of accounting for, and control of, nuclear material being taken into account;* (d) *Oversight and enforcement to maintain arrangements for safety, nuclear security and the system of accounting for, and control of, nuclear material;"*
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.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ASN inspectors receive some training on security topics but not on security for nuclear facilities.*	
(1)	**BASIS: GSR Part 1, Para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills."*
S28	**Suggestion: The Regulatory Body should consider incorporating to its training program topics related to safety/security interface of facilities and activities.**

12.3. INTERFACE WITH OTHER AUTHORITIES

Related to the coordination of all these authorities, it is just indicated that regular meetings held by the SGDSN take place on security aspects and in particular in regard to nuclear security issues.

As far as nuclear safety and security interfaces are concerned, the Department for Nuclear Security coordinates with the Nuclear Safety Authority through regular high level meetings (twice a year). A common workgroup has been set up between the two authorities to improve the coordination on safety and security issues. A convention written in 2005 gives more details on how the two authorities work together. This convention should be updated as it was signed by DGSNR (ASN precursor) and High Commissioner for Defence under an organizational structure quite different from current situation (both DGSNR and High Commissioner for Defence belonged to Industry Ministry). There is an expert designated by the ASN in the Expert Groups that advise the Ministry of Ecology, Sustainable Development and Energy on security of nuclear facilities and nuclear transports.

Interfaces between safety and security for emergency preparedness and response have been taken into account. On the one hand security (malicious acts) events have been incorporated by ASN in regulation for BNI to be taken into account by all parties for emergency preparedness and response purposes and in the other hand a single authority the General Secretariat for Defence and Security (SGDSN) is in charge of planning the contingency and emergency response both to a nuclear security and nuclear safety event. Two years ago a general emergency exercise considering all safety and security aspects to confirm the coordination among all organizations involved was carried out. All parties involved are working to improve definition of emergency exercises to include all these aspects in the future.

ASN has not provided any information on whether it is taking any actions to train and coordinate on-site actions by external security forces with the operator so as to ensure that safety considerations are appropriately evaluated.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although inspectors from ASN and from the Department for Nuclear Security have carried out some joint inspections on safety and security issues, ASN considers the number of these inspections to be low. The IRRS team was informed that co-operation in this field is going to be increased.*	
(1)	**BASIS: GSR Part 1, Para 4.35 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including:* *—Liaison with the relevant organization for joint inspections, where necessary."*
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.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The convention for co-operation (memorandum of understanding) signed by the authorities in charge of nuclear safety and nuclear security has not been updated since 2005.*	
(1)	**BASIS: GSR Part 1, Para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. …This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience."*
S30	**Suggestion: ASN should consider updating of the convention for co-operation with authorities in charge of security of nuclear facilities.**

12.4. SUMMARY

For BNI and ICPE facilities two regimes for authorization and control are in force related to safety and security. There are some provision for coordination and co-operation of authorities involved in each one of them but improvements and updating is required.

ASN need to have higher involvement in security issues. Allocation of responsibilities to ASN in this field could be useful.

ASN has to consider including topics on security issues in its training program, taking into account the activities being carried out currently on security safety interfaces

Actions to promote having a regulatory framework in force and implemented for the security of radioactive sources are considered very necessary to comply with international recommendations and with the commitments taken by French State.

13. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

13.1. IMMEDIATE ACTIONS TAKEN BY THE REGULATORY BODY

Emergency response by the regulatory body

On the day of the TEPCO Fukushima Daiichi accident the ASN activated its emergency response centre. The activity of the emergency centre was modified according to the requirements set by the accident and was dominated by the collection of information and data, providing information to the government, to other authorities and governmental institutions and to the general public on the situation in Japan and on its consequences on France and its citizens. Accordingly the emergency team consisted of a technical part [leader, two technical evaluators, two (later on one) radiation experts, two (later one) logistics staff] and a communication part (leader, three press officers, spokespersons). Spokespersons were selected from leading experts of ASN (Commissioners, DG, DDG and directors).. The emergency centre was operational 24/7 until April 13, 2011 and with decreased operation for a longer period of time. Almost half of the ASN staff (200 persons) took part in the work of the emergency centre. Commissioners and members of the General Directorate regularly participated in the work in the centre.

The emergency centre held daily conferences with IRSN, with the Incident and Emergency Centre of IAEA, and with several foreign regulators. Similarly daily communication was held with the emergency unit at the French embassy in Japan, where an expert of IRSN was sent as adviser to the Embassy.

On April 20, 2011 ASN recommended the government to initiate contamination measurements of the goods arriving from Japan. French citizens travelling to, returning from or staying in Japan were advised on the radiological situation and actions to be taken.

From the end of March 2011 a systematic detection of radioactivity had been carried out on goods transported from Japan by air, under the responsibility of the concerned airlines in (either before departure from Japan or after arrival to France). From 11th of April 2011, maritime containers from Japan were sampled and checked by French customs upon their arrival at the ports of Havre and Marseille. No positive detection cases reported to ASN.

Public communication

The communication service prepared 45 press releases, held 17 press conferences, operated a press centre in ASN's headquarter where daily press conferences were held between 16 and 25 March. ASN satisfied about 1500 media requests; the spokespersons gave about 1000 interviews.

A call centre was operated in ASN, where complex questions were answered by ASN experts. A dedicated website was opened on March 13 to inform the public in a comprehensive manner. The website was visited more than 70.000 times a day. Also the social media was used for communicating with the public. ASN created Twitter and Facebook entries to post its press releases and videos.

Various aspects of the communication presented challenges for ASN public communication: intense media pressure; completion and compilation of information arriving from Japan; maintaining in active mode the crisis organization for a long period of time. ASN obtained favourable feedback from its media partners concerning its availability, openness and competence. That feedback was confirmed by opinion surveys conducted after the accident.

Safety evaluations promptly required by the regulatory body

On March 23, 2011 the Prime Minister requested ASN to initiate a safety assessment of the civil nuclear facilities complementary to the existing safety assessments. This complementary assessment was also extended by 12 resolutions in May 5, 2011 by ASN to respond to the request by ENSREG on initiating a targeted safety re-evaluation of the nuclear power plants in the EU member states (called stress test – ST).

The complementary safety assessment was aimed at the re-assessment of the safety margins of the nuclear facilities from the point of view of the most important initiating events playing a role in the TEPCO Fukushima Daiichi accident: earthquakes, flooding, extreme weather conditions, loss of electrical power, loss of ultimate heat sink, severe accident management and emergency preparedness and response. The assessment was expected to consider three important aspects:

- conformity of the steps taken and of the actual status of the facilities with the design requirements
- robustness of the facilities against beyond design basis events, possible cliff-edge effects and the measures taken against them
- Possible safety improvement measures

Unlike in many other European countries, the French ST was not limited to the 58 existing power plants and the one under construction but was also extended to 20 other nuclear facilities of high safety importance (research reactors, fuel cycle facilities, etc.) as well as to 72 other facilities for which the lessons learned from the accident may have safety implications. Details of the assessments are given in the next section.

Inspection activities by the regulatory body

Following the accident, ASN adjusted its inspection program to include the specific issues raised by the accident. Thus a series of 38 targeted inspections were held in June to October 2011 covering all French NPPs to scrutinize the licensee's technical and organizational compliance with the safety requirements. The inspections were focused on protection against the events characterizing the accident, i.e. off-site natural hazards, loss of electrical power, loss of heat sinks as well as on emergency preparedness and response. 40 follow-up inspections were conducted to check the correction of the deficiencies revealed during the targeted inspections in 2011.

Lessons learned from the immediate actions

Following the immediate actions, ASN carried out an examination of its crisis activity and its cooperation with other participants in order to draw conclusions on the necessary changes. ASN concluded that certain modification might make the activity of the organizations taking part in the emergency activity more effective and efficient. At the national level ASN suggested that

- a direct line should be set up between ASN Commission and the Presidency of the Republic in order to shorten the time needed for communication.
- a technical strategic management command post should be established in the ASN emergency response centre. It should keep contact with its technical support organization, IRSN, and with the ASN Commission in order to alleviate advising the Prefect, who acts as the director of emergency operations;
- a communication command post should be established in the ASN emergency response centre. It should keep constant contact with other actors in communication (Prefect, licensee, IRSN, ministries).

At the local level it was suggested that

- ASN representatives should work with and advise the Prefect in his decisions;
- ASN inspectors on the damaged site should forward the decisions taken at the national level and should monitor the decisions taken by the licensee.

13.2. TECHNICAL AND OTHER ISSUES CONSIDERERED IN THE LIGHT OF THE ACCIDENT

In line with the initiatives by the European Commission and the European Nuclear Safety Regulators Group (ENSREG), France participated in the targeted safety re-evaluation (Stress Test) of its nuclear power plants. By definition the ST addressed earthquake, flooding and other extreme natural events (also in combinations) as well as potential loss of safety functions (electrical power and/or ultimate heat sink), severe accident management and emergency preparedness and response. Beyond the scope defined by ENSREG, the French regulatory body required the completion of stress test exercises for research reactors, fuel cycle facilities, waste storage facilities and for many other facilities that may have an impact on the nuclear and radiation safety. The results of the assessments related to the French NPPs are briefly discussed below.

Stress Test results and regulatory position

The complementary safety assessment (CSA) and ST extended over the initiating events as required by EC and ENSREG, i.e. earthquakes, floods, extreme weather conditions, loss of external electrical power, loss of ultimate heat sink and severe accident management, including emergency preparedness and response.

The first step of the investigations in all cases was related to the management of deficiencies with the existing baseline safety standards. In this respect ASN concluded that although the existing system of EDF for managing deficiencies (in particular via periodic testing, maintenance and periodic safety assessment) is satisfactory the CSA and ST identified deviations and other opportunities for further development. In response to that ASN requires the licensee to strengthen its processes for detecting deficiencies and also to put in place a process for assessment of the cumulative effects of deficiencies detected.

For earthquake protection the CSA and ST demonstrated that the seismic margins available in the French NPPs are sufficient for protection against the majority of reasonably foreseeable seismic events while in case of more serious events no cliff edge effects may occur. ASN required a number of specific actions to increase seismic safety of the French NPP fleet as detailed in a subsequent subsection.

In case of flooding the event at the Le Blayais NPP in 1999 called for a thorough reassessment of the flooding risks and a number of related measures were initiated to yield a high level of protection of the French NPPs against floods. The CSA and ST concluded that some of these measures have not been completed, while specific steps related for “volumetric protection” (coverage of volumes with non-penetrable layers) and for the prevention of clogging could effectively contribute to the increase in safety.

Hazards resulting from the presence of industrial facilities and their possible effects on the NPPs were also examined. Since little information is available on the robustness and accident scenarios of such facilities, ASN required EDF to perform such analysis and determine the hazards and risks represented by such facilities in case of extreme events investigated in the framework of the CSA and ST.

Analysis of beyond design basis scenarios that may lead to loss of electricity supply and/or loss of ultimate heat sinks, possibly combined with other extreme natural events shows that in unfavourable situations and without intervention the core may melt within a few hours. To cope with such situations ASN requested EDF to take effective measures to provide emergency water supply, review the heat sink design and reinforce management of consequences of such situations. More on these regulatory requirements are given in a subsection below.

A review of severe accident and emergency management in the framework of CSA and ST revealed a number of issues especially when long lasting, multi-unit emergencies occur due to beyond design basis initiators.

In a position paper of January 3, 2012 ASN drew the main conclusions of the complementary safety assessment and of the ST. Accordingly, there is no need for immediate shutting down of any French nuclear facility, yet there is a need to extend the robustness of the facilities against extreme initiating events falling beyond the design basis.

The most important measures stemming from the complementary assessment concerned the requirement for designing and implementing a so called "hardened safety core" in each nuclear power plant and to establish fast reacting emergency response teams to be available for each nuclear power plant. The two measures are detailed in the next subsections. Further regulatory requirements resulting from the ST will be quoted in brief in a subsequent subsection.

The "hardened safety core" concept

On June 26, 2012 ASN issued a set of resolutions on requiring EDF to implement measure aimed at strengthening the safety in its nuclear power plants by, among others, the establishment of hardened safety cores. This hardened safety core concept was proposed by IRSN.

The main purposes of the hardened safety core are:

- prevention of the accident from reaching fuel melt or if prevention fails, mitigation of consequences
- mitigation of large-scale radioactive releases
- enabling the licensee to perform its emergency management and response obligations

It is to be stressed that the hardened safety core concept involves the implementation of measures and equipment that are meant to prevent or mitigate events well beyond the design basis. The hardened safety core includes a bunkered alternate ultimate heat sink and water supply system for the primary circuit, reactor confinement and fuel pools. It also includes an additional ultimate electricity generating set, new crisis management premises habitable in the long term in all circumstances, mobile emergency preparedness devices and means of communication, and additional instrumentation. A schematic picture of the hardened safety core is given in the figure below (courtesy of ASN).

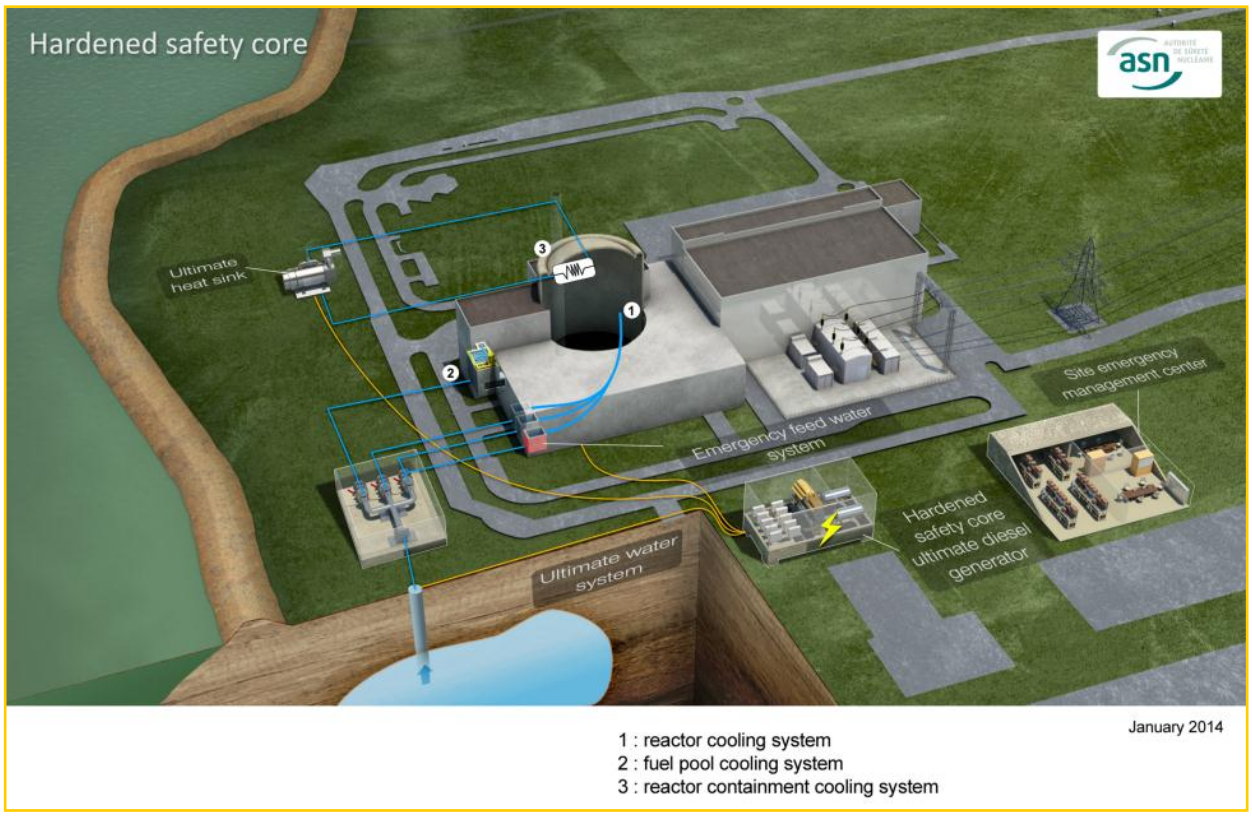

Figure 2: Hardened Safety Core

The hardened safety core is expected to be functional without any external intervention for three days and, after refuelling and performing the necessary checks and maintenances, for 10 days.

In a resolution of January 21, 2014 ASN further detailed its requirements on the hardened safety core and set the goals of

- prevention of core melt by giving priority to cooling by the secondary system
- ensuring the performance of the containment
- providing containment cooling without venting

The resolution requires that EDF define the list of SSCs together with their qualification requirements, the seismic hazards related to the hardened score assuming a return period of 20 000 years, as well as requirements related to other external hazards; verify the structural resistance and prevention of fuel drying of the fuel pools under circumstances assumed for the hardened safety core; ensure ability of control rod drop and provide independence of the hardened safety core I&C from the existing systems.

The timeline for the implementation will be discussed in a following section.

Fast response nuclear team

In its June 26, 2012 resolutions ASN required EDF to establish fast response nuclear teams (FARN) that are able to intervene in any NPP in France within 24 hours without any external assistance. These teams need to be able to take over the duties of the operational personnel; to provide additional emergency response resources and to cope with the accident of multiple units at a site.

The concept of FARN complements the hardened safety core concept in the sense that until the time FARN is ready to a full scale intervention (24 h), the hardened core has in all circumstances the capability to withhold adverse effects of an accident on the public.

Implementation timeline

The implementation of the safety measures related to the implications of the TEPCO Fukushima accident is to be completed in three phases. The first phase covers 2012-2015 and includes the creation of FARN, and the establishment of mobile and temporary "plug & play" solutions for emergency power sources and water sources. In the second phase, between 2015 and 2019 the hardened safety core is to be established in all NPPs in a scope that will be able to cope with the most of extreme events considered in the light of the accident. The third phase is planned to end in the framework of the next PSR and is to result in a setup able to prevent most of the beyond design situations, large and long-lasting radioactive releases and, in the event of an incidental release, to be able to assist in its mitigation.

Other issues considered by ASN

In the conclusions on the ST by ASN, the first and the last one addressed the hardened safety core and the fast response nuclear team, respectively. The other 34 conclusions pertain to the four other issues stemming from the lessons learned from the accident: earthquakes, flooding, water and electricity supplies and emergency preparedness and response. The conclusions may be summarized as below.

For seismic protection the actions required by ASN are related to seismic instrumentation; preventing unwanted interactions of various components; preparations and training of personnel; seismic resistance of fire-fighting system and studying the implementation of automatic shutdown in case of earthquakes. In the field of protection against flooding ASN requires specific actions related to the experience feedback in case of Blayais NPP and to the robustness of two other NPPs against floods, the establishment of "volumetric protection" and reinforcement of other protective means. For water and electricity supply the main issues are the heat-sink design; emergency water supply; management of long term LOUH and LOEP and additional electrical power supplies.

Besides establishing FARN, 13 additional requirements address emergency management issues and, among others fuel pool investigations, management and instrumentations; safety of fuel handling; design, pressure management and venting filtration of the containment; design and use of emergency management premises and handling multiple unit emergencies. In order to cope with these requirements EDF shall take measures to limit radioactive releases in case of core melt, propose improvements in the venting and filtration system of containment and implement technical measures to establish "geotechnical containment". Skilled and trained personnel should be available in necessary numbers to cope with the foreseen emergency situations.

In connection with emergency preparedness and response, it is to be mentioned that the Prime Minister initiated a comprehensive review of the national emergency planning in order to understand all aspects to be taken into account in a nuclear or radiological accident with potential major impact on France. With the participation of the major players in emergency preparedness and response (ministries, ASN, operators, other expert institutions), a national plan on "Major Nuclear or Radiological Accidents" was elaborated and published on February 3, 2014.

A separate part of the regulatory position paper dealt with priorities related to the social, organizational and human factors. ASN stated that renewal of the workforce and skill is fundamental for the future of nuclear safety. Problems related to subcontractors need higher attention whereas further research activities need to be initiated at both national and European levels.

ASN activities related to the IAEA Nuclear Safety Action Plan

France the country with the largest nuclear programme in Europe as well as a signatory party of the Convention on Nuclear Safety and of several other international conventions in the field of nuclear applications, considered it important to regularly report on its progress reached on the actions taken in support of the IAEA Nuclear Safety Action Plan (NSAP). At the time of the IRRS mission the latest available report was dated May 2014. According to the report 21 actions had been completed, 13 actions are being regularly or permanently performed, 20 were ongoing/ in progress and no action foreseen by NSAP was left without French reaction. Typical completed actions are those related to the TEPCO Fukushima Daiichi accident (yet many such actions are also ongoing), capacity building, transparency and communication effectiveness. Regular and permanent actions are typically those related to peer reviews, participation in conventions and international cooperation. Actions are ongoing on the review of emergency preparedness, follow-up of stress test exercises and in research and development.

Public opinion

The image of ASN as reflected by public opinion is surveyed since 2005. The survey is meant to measure the visibility and recognition of ASN in two representative samples of the public: general public and individuals that are expected to be informed more than the average in nuclear issues. The survey conducted in October to December 2011 reflected a clear increase in both the awareness/visibility and the recognition of ASN. Specifically ASN was known to 37% of the general public, which is a net increase by 13% compared to 2010. The corresponding numbers among the informed public were 88% and 79%.

61% have heard about ASN's actions (+ 15 pts over 2010) and 72% have heard ASN discussing the Fukushima accident. Among those who heard ASN discussing Fukushima, a majority (70% of the general public and 77% of the more informed public) are satisfied with what they heard. Knowledge about the role and activity of ASN has also shown some increase among the public after the TEPCO Fukushima Daiichi accident.

CONCLUSION [1]

The IRRS Team concluded that the nuclear and radiation safety regulatory body in France took timely, appropriate and extensive actions in reply to the implications of the TEPCO Fukushima Daiichi accident. The Team considers it commendable that the complementary safety assessment was extended to all French nuclear facilites that may be affected by a beyond design basis accident. It is also believed that the concept of hardened safety core may serve as an option to be considered for further development of the general nuclear design safety concept.

13.3. PLANS FOR UPCOMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE ACCIDENT

The National Action Plan (NAcP) presented to the IRRS Team is an updated form of the plan originally submitted for discussion to ENSREG in December 2012. It contains the actions of the licensee and of the national organizations resulting from the stress test exercise of the French nuclear power plant as of April 2014.

The major actions in the NAcP relate to the practical implementations of the ASN decisions mentioned in the previous section in connection with the various hazard topics i.e. natural hazards (seismic effects, flooding, secondary effects); loss of safety systems (cooling and alternate heat sink, electrical power supply and backup batteries, instrumentation, coolant pumps,

ventilation, control room, spent fuel pool, etc.) and severe accident management (equipment resistance, EPR in extreme conditions, SAMGs, training and exercise, hydrogen and water management, etc.).

The deadlines in the NAcP are between 2012 and 2018 and define periods for studies and investigations and for implementation. The full establishment of hardened safety cores takes the longest time and shall be completed in 2018; other measures related to seismic risks have been completed by 2014. Measures related to flooding risks are expected to be completed in 2015 and the same is true for the actions related to the emergency water and electricity supply not included in the hardened safety core developments. Severe accident management covers a great number of actions many of them (e.g. containment melt-through and hydrogen instrumentation, rapid drainage of fuel pools, seismically safe emergency premises and full establishment of FARN) schedules to be completed in 2016 or later.

The action plan dedicated a chapter to the actions to be taken by the national organizations including ASN and its TSO IRSN. Their coordinated tasks in nuclear and radiological emergencies are:

- validating and supervising the actions by the licensee
- advising the government and the Prefects on the measures to take
- dissemination of information
- acting as a competent authority in international relations

Based on the experience and feedback collected from the TEPCO Fukushima Daiichi accident, ASN and IRSN concluded in a number of statements regarding their future actions in emergencies.

As for a possible large scale mobilization, ASN and IRSN concluded that "*a nuclear accident occurring closer in Europe would lead to the mobilization of all their resources to respond to the needs of the French authorities and an accident in France would raise real difficulties in terms of human and material resources*".

They acknowledge the importance of coordinated international actions in case of emergencies and state that "*the lack of harmonization in public protection measures can be prejudicial to the credibility of the action undertaken and to confidence in the public authorities*".

They consider communication with the various possible audiences essential including the need to use every possible communication channel and giving access to the measurement and analysis data to the public.

The most important actions foreseen by ASN for itself are the training of its personnel, the development of guides on management of long lasting emergencies and the establishment of a new emergency centre in Montrouge (that has since been completed). There are no actions foreseen by ASN regarding its working methods in the core regulatory functions (authorization, review and assessment, inspection, enforcement, preparation of regulations and guides).

CONCLUSION [2]

The IRRS Team concluded that the possible implications of the TEPCO Fukushima Daiichi accident on nuclear and radiation safety in France were thoroughly assessed and the actions that may further enhance the nuclear and radiation safety in the country in general and the safety of the operating nuclear power plant specifically were determined and scheduled for implementation in the National Action Plan. This Action Plan included a number of actions to be taken in order to enhance its capability to respond to large

CONCLUSION [2]
scale, long lasting emergencies. ASN has also emphasized the importance of international cooperation and concluded that further effective steps are needed in order to make sure that the regulatory body is capable of delivering its emergency response reponsibilities in a long lasting nuclear emergency within or in the vicinity of France.

13.4. CONCLUSIONS BY THE REVIEWED AREAS

Note: ***The significance of the Fukushima implications was considered as part of the review of each IRRS module. The review conclusions below and the plans presented by France to further address TEPCO Fukushima Daiichi issues in the coming years should be included in the scope of the follow-up IRRS mission to be invited by France.***

Module 1: Responsibilities and Functions of the Government

The review carried out in light of the TEPCO Fukushima Daiichi accident has not identified specific vulnerabilities in the area of the responsibilities and functions of the government.

Responsibilities are clearly allocated in the governmental legal and regulatory framework for safety also in emergency/accident situations. In the event of an emergency/accident situation, several authorities are involved, and their respective responsibilities and functions are clearly specified within the governmental, legal and regulatory framework for safety also for emergency/accident situations. A complete set of co-operation agreements have been signed by ASN with all competent authorities.The role of the authorized party is clearly specified.

In relation to regulatory independence some concerns have raised during the IRRS mission as it has been found that Environment Code allocates responsibilities on nuclear safety to the Government being in charge for national energy policy. A Recommendation has been proposed to increase independence of ASN.

Adequate availability of dosimetry capabilities has been found for planned exposure situations. For emergency situations enough capabilities exits for public doses estimation and for dose surveillance of workers

CONCLUSION [3]
For the topics in the area of the responsibilities and functions of the government the existing status is appropriate and no concern has been raised.

Module 2: Global Nuclear Safety Regime

The review carried out in light of the TEPCO Fukushima Daiichi accident has not identified specific vulnerabilities in the area of the global nuclear safety regime.

France has ratified all relevant international conventions. The French Government (represented by ASN) is an active participant in the CNS. ASN is an active participant in international activities through IAEA, CE, ENSREG, WENRA and HERCA and it also maintains agreements for bilateral co-operation with many other regulatory bodies, including all neighbouring countries. France demonstrates openness for, and a strong involvement in international peer review missions.

CONCLUSION [4]
In the area of the global safety regime no concern has been raised and the IRRS Team concludes that the existing status is appropriate.

Module 3: Responsibilites and Functions of the Regulatory Body

The Environmental code gives ASN the authority to intervene in any facilities or activities that presents significant radiation risks, irrespective of the possible costs to the authorized party. This right also includes decisions taken in case of an emergency. In France, the Prefect acts as the director of emergency operations (for further information see Module 10 Emergency Preparedness and Response).

The conditions to alert the public are defined within decree 2005-1269 of October 12, 2005. Four national conventions cover the national warning messages. The Ministry of Interior is currently upgrading the warning and information system (SAIP) which includes a network of sirens and alert messaging systems.

ASN has its own provisions for communicating in emergency situations through its website, media releases, press conferences and call centre. There were many improvement actions identified by ASN in the communication area as a consequence of the TEPCO Fukushima Daiichi accident.

CONCLUSION [5]
The IRRS Team considers that, in relation to its functions and organization the regulatory body is ready to act appropriatly and the necessary further actions have been initiated.

Module 4: Management System of the Regulatory Body

The ASN management system has evolved over time and the first version of ASN's integrated management system, documented in the management system manual, was issued in 2012. However, there are some observations concerning the comprehensiveness of the current management system (see Chapter 4). To continuously improve its management system, ASN uses self-assessment tools, internal audits and reviews and ASN has a performance indicator system.

ASN regularly assesses its resource needs but the long-term staffing and competency planning could be further improved (see Chapter 3 on Responsibilities and Functions of the Regulatory Body). Management system should also better promote regulatory safety culture (see Chapter 4).

CONCLUSION [6]
The IRRS Team considers that the regulatory body had already planned some necessary further improvements of its management system. Certain further actions are suggested (see Chapter 4).

Module 5: Authorization

The French system for providing authorization for all facilities and activities is described in the environment code and associated decrees and orders. The licensing process has not been modified as a consequence of the TEPCO Fukushima Daiichi accident.

Stress Tests were carried out in France in compliance with the request by the European Council and the French Prime Minister. The analyses were carried out according to the specifications drafted at the European level with two extensions:

- The Stress Tests (ST) conducted in France concerns all nuclear facilities, including research facilities and fuel cycle plants; in particular Stress Tests were conducted also for the Flamanville 3 unit which is currently under constructions.
- The specifications were supplemented by points concerning the use of subcontractors, which was also assessed.

Details on the ST are given in sections 13.2 and 13.3 above. The specific back-fitting measures identified as a result of the ST require plant modifications. The authorization of such modifications will be followed-up by the regulatory body within the established authorization system.

Finally, following the Fukushima accident, the Prime Minister asked the General Secretariat for Defence and National Security (SGDSN) to conduct a comprehensive planning effort to understand all aspects of a severe nuclear accident either in France or abroad in case there would be a major impact at the country level. In connection with all stakeholders (ministries, ASN, expert agencies, operators), the SGDSN led the development of the National Plan "Major Nuclear or Radiological Accident", which was published February 3, 2014. ASN departments contributed to the development of this plan, by leading or contributing to the writing of ten factsheets on particular actions to protect people, information, public and post-accident management. The work of the Steering Committee for the management of post-accident phase of a nuclear accident or radiological emergency (CODIRPA), led by ASN since 2005, were used to develop part of the plan devoted to the output of the emergency phase.

CONCLUSION [7]
The IRRS Team considers that, with respect to the TEPCO Fukushima Daiichi accident no concern related to the authorization process was raised.

Module 6: Review and Assessment

The main activity in the area of review and assessment in relation to the TEPCO Fukushima Daiichi accident, has been conducted by the regulatory body in the frame of the Stress Tests according to the ENSREG specifications: Stress Tests were performed for all nuclear facilities and with an extension of scope related to the management of subcontractors.

As a result of the review of the file submitted by the licensees, a series of actions has been requested by ASN for implementation at the nuclear facilities and in general by the licensees. The actions divided in short, medium and long-term measures will allow reaching a significant reinforcement of the safety margins of the facilities beyond their design-basis levels.

In particular, as a result of assessment of allowable hazards and risks EDF has been required to set up a “hardened safety core” of material and organisational measures to control the fundamental safety functions in extreme situations. Details on the resulting safety enhancing measures are discussed in sections 13.2 and 13.3.

CONCLUSION [8]

The IRRS Team considers that the actions taken by the regulatory body in the context of the complementary safety evaluations were appropriate. These were based on the results of the European Stress Tests as per ENSREG specifications plus an extension of scope as related to the management of subcontractors. The necessary back-fittings and improvements leading to a significant reinforcement of the safety margins of the facilities beyond their design basis have been planned and are being followed-up by the regulatory body within the regular oversight processes.

Module 7: Inspection

After the TEPCO Fukushima Daiichi nuclear accident in 2011, ASN adapted its inspection programme to reinforce checks on all the French nuclear facilities considered to be high-priority. 38 targeted inspections, representing 110 on-site worked days, involved spot checks of the conformity of the licensee's equipment and organisation with the existing baseline safety standards. These targeted inspections were planned to reassess the status of all NPPs regarding the following topics:

- protection against off-site hazards, in particular the ability to withstand earthquakes and protection against flooding,
- loss of electrical power supplies (LOOP),
- loss of heat sinks (LUHS),
- operational management of radiological emergency situations.

The inspections reviewed both on site and off site means for ensuring these safety functions available in case of an emergency.

Inspections focused on the LOOP and LUHS were done also for the storage facility as well as for the reactor.

In addition to the targeted inspections, ASN performed the EU stress tests.

The targeted inspections of the topic "operational management of radiological emergency situations" assessed the actual arrangements between the operator's headquarters and the plant management in case of an emergency.

Inspections were conducted also to check and verify procedures and agreements between operator's and relevant organizations. Several national exercises involved national and local organization.

CONCLUSION [9]

The IRRS Team concluded that ASN has expanded its standard inspection programe in 2011 and 2012 to verify the implementation of measures taken to date by the operator in response to the TEPCO Fukushima Daiichi accident. Since 2013, ASN inspections focus on implementation of post-Fukushima measures which are performed within the scope of ASN standard inspection plans. The IRRS Team considered that ASN acted as necessary.

Module 8: Enforcement

ASN is empowered to impose corrective measures and enforce their adoption, including sanctions in the case of failure to observe the measures by relevant Codes. The licensee's post-Fukushima action plan has been submitted to ASN. Completion times for implementation are being monitored. The IRRS team concluded that ASN is fully capable to implement the enforcement process with independence and authority in the case of any implication of the TEPCO Fukushima Daiichi accident

CONCLUSION [10]
The IRRS team concluded that the lessons learned from the TEPCO Fukushima Daiichi accident had no implications for ASN enforcement activities. With respect to this and taking into account the assessment of the IRRS team in Chapter 8, there is no need to change the ASN's enforcement process in place with respect to lessons learned from the TEPCO Fukushima Daiichi accident.

Module 9: Regulations and Guides

Following the Fukushima Daiichi accident, ASN prepared a decision on the NPP licensees (June 26, 2012) to implement a hardened safety core. This concept is meant for guaranteeing the safety functions even in beyond design situations. The hardened safety core will include i.e., an ultimate bunkered alternate heat sink and water distribution systems, an ultimate diesel generator, and premises for emergency management (see also in section 13.2). ASN has completed some of the design requirements of this hardened safety core through ASN resolutions (January 21, 2014). In addition, the June 2012 decision required additional provisions for a long duration emergency.

ASN is actively participating in the work of WENRA for the harmonization of nuclear safety requirements. In October 2014 WENRA published the updated reactor safety reference levels (RLs) based on the lessons learnt from the TEPCO Fukushima Daiichi accident. ASN has a plan to include the lessons learnt from Fukushima in the French regulations.

ASN guide on external flooding was published in 2013, ASN is currently updating the guide on the design of NPPs. It will incorporate strengthened requirements taking into account recent international publications and lessons learnt from Fukushima Daiichi accident

CONCLUSION [11]
The IRRS Team considers that in relation to regulations and guides, the regulatory body is committed to act as necessary and actions have been initiated.

Module 10: Emergency Preparedness and Response

As a result of the Fukushima Daiichi accident, the NPP operating organization has conducted stress tests and taken immediate actions to enhance the robustness of emergency response arrangements, including the provision of mobile equipment for power supply and core cooling at the site, plans for the construction of fixed equipment and the establishment of a rapid action force for nuclear emergencies (FARN). Off-site plans have been reviewed and revised, and is in the process of a second revision. Operators have the capability to warn the public of an

emergency situation for fast kinetic events. The ASN conducts inpection of severe accident management guidelines and of the deployment of the FARN.

Severe accidents with uncontrolled release are not taken into account in the threat/hazard assessment, which is the basis for the early phase offsite emergency plans. However, the post accident strategy does not limit itself to design basis accidents and is currently examining the implications of severe accidents with protracted releases and greater distances affected.

CONCLUSION [12]
In the area of emergency preparedness and response, the IRRS Team considers that appropriate actions have been taken and further actions have been initiated

IRRS FRANCE REVIEW TEAM

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APPENDIX II - MISSION PROGRAMME

Time	16-SUN	17-MON	18-TUE	19-WED	20-THU	21-FRI	22-SAT	23-SUN	24-MON	25-TUE	26-WED	27-THU	28-FRI
08:00-09:00	Arrival of Team Members	**Team Meeting**	**Team Meeting**	**Team Meeting**	**Team Meeting**	**Team Meeting**	Free	SOCIAL EVENT	TM discussion of Recommendations, Suggestions and Good Practices	TM finalize Draft Report	TM and Admin. Assistant finalize Draft Report	ASN reviews Draft Report	**Exit Meeting**
09:00-10:00		Entrance Meeting	Interviews/Site visits	Interviews/Site visits	Interviews/Site visits	Interviews/Site visits	TM review/discuss Draft Report						**Press Conference**
10:00-11:00	IRRS Refresher Training												Departure of IRRS Team Members
11:00-12:00													
12:00-13:00		Lunch	Lunch	Lunch	Lunch	Lunch	Lunch		Lunch	Lunch	**Submission of Draft Report to ASN**	ASN returns Draft Report with comments/mark-ups to IRRS Team	
13:00-14:00		Interviews	Interviews/Site visits	Interviews/Site visits	Interviews/Site visits	Interviews/Site visits	TM review/discuss Draft Report		TM write Report	**Policy Issue Discussion on "Safety/Security interfaces"**	**ASN reviews Draft Report**	TM review ASN comments and amends Draft Report	
14:00-15:00									**Policy Issue Discussion on "Resources allocated to the regulatory body, the technical support organizations and the corresponding funding schemes"**				
15:00-16:00	Initial Team Meeting											**Plenary meeting with ASN to discuss comments**	
16:00-17:00													
17:00-18:00		**Daily Team Meeting**	**Daily Team Meeting**	**Daily Team Meeting**	**Daily Team Meeting**	**Daily Team Meeting**	TM write report and submit to Admin. Assistant	TM write Report and submit to Admin. Assistant	**Daily Team Meeting**	**TM finalize Draft Report**		**TM and Admin. Assistant finalize Draft Report and submit final version to ASN**	
18:00-19:00		Dinner	Dinner	Dinner	Dinner	Dinner	Admin. Assistant edits Draft Report and forwards to TM		Dinner	Dinner		TL/DTL prepares exit meeting presentations and IAEA press release	
19:00-20:00	Free												
20:00-24:00		Team Members (TM) write findings	TM write findings	TM write Report and submit to Admin. Assistant Admin. Assistant compiles Draft Report	TM write Report and submit to Admin. Assistant Admin. Assistant edits Draft Report and forwards to TM	TM write Report and submit to Admin. Assistant Admin. Assistant edits Draft Report and forwards to TM		Admin. Assistant edits Draft Report and forwards to TM	TM write Report and submit to Admin. Assistant Admin. Assistant edits Draft Report and forwards to TM	TM finalize Draft Report and submit to Admin. Assistant Admin. Assistant edits Draft Report and forwards to TM		Farewell Dinner	

APPENDIX III - MISSION COUNTERPARTS

	IRRS Experts	ASN Lead Counterpart	ASN/IRSN Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	RODRIGUEZ, Manuel PETŐFI, Gábor YAMADA, Tomoho	Jean-Christophe NIEL	Philippe JAMET Jean-Jacques DUMONT Alain DELMESTRE Henri LEGRAND Vanessa COTTIN M. SCHULER
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	RODRIGUEZ, Manuel PETŐFI, Gábor YAMADA, Tomoho	Stéphane PAILLER	Anne PILLON MG ALBERT
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	HALL, Andy ALM-LYTZ, Kirsi	Nicolas OSOUF	Henri LEGRAND Anne-Cécile RIGAIL Vanessa COTTIN P. DESCHAMPS
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	HALL, Andy ALM-LYTZ, Kirsi	Corinne LAVIGNE	Emmanuelle MARTEL P. DESCHAMPS

	IRRS Experts	ASN Lead Counterpart	ASN/IRSN Support Staff
5.	**AUTHORIZATION**		
	SARDELLA, Rosa MANSOOR, Faizan SHIN DaeSoo CHEONG, Jae Hak SMIDTS Olivier SCOTT, Jim BENIDER, Abdelkader SAMPSON, Michele	Vivien TRAN-THIEN Philippe DUPUY Pierre NOUALHAGUET Thomas HOUDRÉ Christophe KASSIOTIS Fabien SCHILZ Pierre JUAN Sylvie RODDE Guillaume BELOT Colette CLEMENTÉ	Olivier ALLAIN F. BIGOT Vanessa COTTIN Martine BAUDOIN Jean-Jacques DIANA Eric LE COZ I. LEBARS
6.	**REVIEW AND ASSESSMENT**		
	SARDELLA, Rosa MANSOOR, Faizan SHIN DaeSoo CHEONG, Jae Hak SMIDTS Olivier SCOTT, Jim BENIDER, Abdelkader SAMPSON, Michele	Vivien TRAN-THIEN Philippe DUPUY Pierre NOUALHAGUET Thomas HOUDRÉ Christophe KASSIOTIS Fabien SCHILZ Pierre JUAN Sylvie RODDE Guillaume BELOT Colette CLEMENTÉ	Olivier ALLAIN F. BIGOT Vanessa COTTIN Martine BAUDOIN Jean-Jacques DIANA Eric LE COZ I. LEBARS
7.	**INSPECTION**		
	WILDERMANN, Thomas	Bénédicte GENTHON	Jean-Luc LACHAUME

	IRRS Experts	ASN Lead Counterpart	ASN/IRSN Support Staff
	TIPEK, Zdenek SHIN DaeSoo CHEONG, Jae Hak SMIDTS Olivier SCOTT, Jim BENIDER, Abdelkader SAMPSON, Michele	Ambroise PASCAL Christophe KASSIOTIS Fabien SCHILZ Pierre JUAN Sylvie RODDE Guillaume BELOT Colette CLEMENTÉ	Olivier ALLAIN Vanessa COTTIN Martine BAUDOIN Jean-Jacques DIANA Eric LE COZ I. LEBARS
8.	**INSPECTION**		
	WILDERMANN, Thomas TIPEK, Zdenek SHIN DaeSoo CHEONG, Jae Hak SMIDTS Olivier SCOTT, Jim BENIDER, Abdelkader SAMPSON, Michele	Bénédicte GENTHON Ambroise PASCAL Christophe KASSIOTIS Fabien SCHILZ Pierre JUAN Sylvie RODDE Guillaume BELOT Colette CLEMENTÉ	Jean-Luc LACHAUME Olivier ALLAIN Vanessa COTTIN Martine BAUDOIN Jean-Jacques DIANA Eric LE COZ I. LEBARS
9.	**REGULATIONS AND GUIDES**		
	HALL, Andy ALM-LYTZ, Kirsi SHIN DaeSoo CHEONG, Jae Hak SMIDTS Olivier SCOTT, Jim BENIDER, Abdelkader SAMPSON, Michele	Fabien FERON Jacques DEVOS Vanessa COTTIN Christophe KASSIOTIS Fabien SCHILZ Pierre JUAN Sylvie RODDE Guillaume BELOT	F. BIGOT Vanessa COTTIN Martine BAUDOIN Jean-Jacques DIANA Eric LE COZ I. LEBARS

	IRRS Experts	ASN Lead Counterpart	ASN/IRSN Support Staff
		Colette CLEMENTÉ	
10.	**EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS**		
	LAFORTUNE, Jeff SIGOUIN, Luc	Bruno VERHAEGHE	O. ISNARD
11.	**ADDITIONAL AREAS**		
	FRIBERG, Eva DEBOODT, Pascal ZERQUERA, Tomas	Jean-Luc GODET Marie-Line PERRIN Pierrick JAUNET	C. ETARD P. SCANFF JC. GARIEL
12.	**INTERFACE WITH NUCLEAR SECURITY**		
	RODRIGUEZ, Manuel PETŐFI, Gábor YAMADA, Tomoho	Jean-Christophe NIEL	Henry de SAXCE M. SCHULER JM. PERES
13.	**REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT**		
	LUX, Ivan	Nicolas OSOUF	Laurent FOUCHER Bruno VERHAEGHE F. BIGOT P. DESCHAMPS

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

AREA	R: Recommendation S: Suggestion GP: Good Practice	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	S1	**Suggestion:** The Government should consider 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.
	GP1	**Good Practice:** The IRRS Team considers that the efforts at the government level in France to establish a framework for the provision of information and the engagement of stakeholders in transparent decision making related to nuclear safety and radiation protection is exemplary. Committees such as the HCTISN and the CLIs to foster participation of interested parties are required by law.
	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 ASNs safety related decisions cannot be vetoed.
	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.
	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.
2. GLOBAL NUCLEAR SAFETY REGIME	-	-
3. RESPONSIBILITIES AND FUNCTIONS OF THE	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 intothe future as ASN's workload increases.

REGULATORY BODY	**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.**
	GP2	**Good Practice: ASN Commissioners, members of Standing Committees and staff are placed under explicit duties to act impartially and to declare that they have no interests that could compromise this.**
	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.**
	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.**
	GP3	**Good Practice: ASN has incorporated measures to achieve transparency, effective public communication and engagement of stakeholders across all its activities and with all its key stakeholders. The IRRS Team considers that its efforts in this regard are exemplary.**
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**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.**
	R6	**Recommendation: ASN should carry out a systematic and comprehensive audit of IRSN's review and assessment activities against ASN's MS requirements.**
5. AUTHORIZATION	**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.**
6. REVIEW AND ASSESSMENT	**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.**
7. INSPECTION	**S9**	**Suggestion: ASN should consider developing a set of internal guidance criteria for initiation of reactive inspections.**
	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.**
	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.**
	S14	**Suggestion: ASN should consider developing a more effective training to address the limited number of transportation inspectors and the turnover in the Divisions.**
8. ENFORCEMENT	**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.**
	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.**
9. REGULATIONS AND GUIDES	**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.**
	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).**
	S19	**Suggestion: ASN should consider completing the process to implement the Public Health Code to require notification by carriers of radioactive material.**
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	**GP4**	**Good practice: The regulatory and legal requirements for nuclear and radiological emergency planning illustrate a very high degree of integration and harmonization with other conventional emergency preparedness at the local and national levels.**
	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.**
	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.**
	GP5	**Good practice: The post-accident management guidelines have been developed, under the leadership of the ASN, and are the result of an extensive concerted dialogue between many different interested stakeholders and neighbouring countries. Work is under way to include as part of this guidance accidents with protracted releases and impacts beyond the emergency planning zones.**
	GP6	**Good practice: The conduct of unannounced exercises at NPPs, evaluated against specific objectives is**

		considered a good practice.
	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.**
	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.**
11. ADDITIONAL AREAS	**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.**
	GP7	**Good Practice: French regulations have set up clear regulatory provisions to describe the management of people in emergency situations.**
	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.**
12. INTERFACE WITH NUCLEAR SECURITY	**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**
	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.**
	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.**
13. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT	**-**	**-**

APPENDIX V - REFERENCE MATERIAL PROVIDED BY ASN

No.	Organization	Document type	Document number/reference	Date	Document title
1	ASN	Procédure	SMQ/DCI/QPR/COM/ASN/000220/2013	00/00/2013	Modalités de réponse aux questions adressées à l'ASN par les parties prenantes
2	ASN	Procédure	SMQ/DCI/QPR/COM/ASN/000210/2012	00/00/2012	Relations Presse
3	ASN	Note	ASN/COM/01	00/00/2008	Information des publics (voir MEA SMQ/100/com)
4	ASN	Décision	n° 2013-DC-0360	2013-07-16	Maîtrise des nuisances et de l'impact sur la santé et l'environnement des installations nucléaires de base
5	ASN	Décision	n° 2014-DC-0417	2014-01-28	Règles applicables aux INB pour la maîtrise des risques liés à l'incendie
6	ASN	Décision	Projet	00/00/2014	Réexamen de sûreté
7	ASN	Décision	n° 2014-DC-0420	2014-02-13	Modifications matérielles des installations nucléaires de base
8	ASN	Procédure	ASN-ADR-01 V3 ASN-ADR-01 V4	00/00/2009	Arrêt de réacteur V3
9	ASN	Note	DCN-ORG-02	00/00/2009	Organisation de la cellule-sites DCN
10	ASN	Lettre cadrage	DCN-2013-053448	2013-10-17	Cadrage monographies
11	ASN	Note	Projet	00/00/2014	Organisation de la cellule REX DCN
12	ASN			00/00/2013	Engagements qualité DCN
13	ASN	Décret	2007-631	2007-04-27	Decret 27 avril 2007 G BESSE II
14	Gouvernement	Arrêté		2013-08-09	Maîtrise des nuisances et de l'impact sur la santé et l'environnement des installations nucléaires de base
15	Premier Min	Circulaire	5567/SG	2012-01-02	Organisation gouvernementale pour la gestion des crises majeures
16	Gouvernement	Décret	2005-1158	2005-09-13	Plans particuliers d'intervention
17	Gouvernement	Arrêté	Homologation de la décision ASN 2009-DC-0153	2009-11-20	Les niveaux d'intervention en situation d'urgence radiologique
18	Gouvernement	Directive interministérielle		2005-04-07	Action des pouvoirs publics en cas de situation d'urgence radiologique
19	ASN	Guide	Guide n° 11	2009	Déclaration des événements significatifs en radioprotection hors installations nucléaires et transport de matières radioactives
20	Gouvernement	Circulaire	DGSNR/DHOS/DDSC	2005-12-23	Principes d'intervention en cas d'événements susceptibles

					d'entraîner une situation d'urgence radiologique hors situations couvertes par un plan de secours ou d'intervention
21	ASN	Note		2014-05-12	Synthèse des actions de coercitions 2013
22	ASN	Note	ASN/SAN/02	1905-06-30	Démarche de l'ASN en matière de détermination des mesures de coercition et des sanctions
23	ASN	Décision	Suspension Radiothérapie	2013-05-17	Décsion 2013 DC 0348
24	ASN	Décision	EDF CNPE BUGEY	2013-04-25	Décsion 2013 DC 0343
25	ASN	Procès Verbal	Modèle de PV		Modèle de procès verbal
26	ASN	Lettre Suite	Revue CNPE Civaux		
27	Gouvernement	Arrêté		2008-07-23	Elimination des effluents et déchets
28	Gouvernement	Code	Code Environnement art R122-5		Code Environnement art R122-5
29	ASN	Fiche	FICHE CONF BUD T2 2015 2016 2017	2014-02-12	Analyse et commentaires sur l'évolution tendancielle de la dépense pour 2015-2017
30	ASN	Note		2014-04-15	Position ASN/IRSN
31	ASN	Politique Qualité			Déclaration de Politique Qualité
32	Gouvernement	Arrêté	SANY0422748A	2004-07-22	Modalités de gestion du risque lié au radon dans les lieux ouverts au public
33	Gouvernement	Arrêté	MTS0818228A	2008-08-07	Gestion du risque lié au radon dans les lieux de travail
34	Gouvernement	Arrêté	SANYO524467A	2005-12-08	Contrôle d'aptitude médicale, surveillance radiologique et contenu des programmes de formation …
35	Gouvernement	Arrêté	ETST134133A	2013-07-17	Carte de suivi médical et suivi dosimétrique des travailleurs exposés aux rayonnements ionisants
36	Gouvernement	Code	Articles R. 1333-15 et R. 1333.16 Santé Publique		Exposition aux rayonnements ionisants d'origine naturelle
37		Code du Travail	Article R.4451-136	2010-07-02	Exposition au radon d'origine géologique
38	Gouvernement	CSP + CT			Extraits Code santé publique
39	Gouvernement	CSP + CT			Extraits codes travail et santé publique DIS
40	Gouvernement	Arrêté	NRD	2011-10-24	Niveaux de référence diagnostiques en radiologie et en médecine nucléaire
41	Gouvernement	Arrêté	Physicien	2004-11-19	Formation aux missions et aux conditions d'intervention de la personne spécialisée en radiophysique médicale

42	Gouvernement	Arrêté	Physicien	2011-12-06	Formation et missions de la personne spécialisée en radiophysique médicale et reconnaissance des qualifications professionnelles des ressortissants étrangers pour l'exercice de ces missions en France
43	Gouvernement	Arrêté	SANYO421830A	2004-05-18	Formation sur la radioprotection des patients exposés aux rayonnements ionisants
44	Gouvernement	Arrêté	Infos dans le CR	2006-09-22	Informations dosimétriques devant figurer dans un compte rendu d'acte utilisant les rayonnements ionisants
45	Gouvernement	Arrêté	art L.1243-1 du code Santé publique	2006-10-23	Fixe le contenu, le format et les modalités de présentation du dossier de demande d'avis au comité de protection des personnes sur un projet de recherche biomédicale portant sur les produits sanguins labiles, les organes, les tissus d'origine humaine ou animale et les préparations de thérapie cellulaire mentionnées à l'article L, 1243-1 du code de la santé publique
46	Gouvernement	Arrêté	Homologation decision 2011-DC-0238 de l'ASN	2011-11-30	Homologation de la décision n° 2001-DC-0238 de l'ASN du 23 août 2011 relative aux qualifications au sens de l'article R.1333-38 du code de la santé publique requises pour les personnes responsables d'une activité nucléaire à des fins médicales
47	Gouvernement	Arrêté		2003-12-01	Qualifications et formation des pharmaciens utilisant des médicaments radiopharmaceutiques dans les établissements de santé et les syndicats inter-hospitaliers
48	Gouvernement	Arrêté		2004-01-21	Information des personnes exposées aux rayonnements ionisants lors d'un acte de médecine nucléaire
49	Gouvernement	Arrêté		2009-06-05	Critères agrément organismes mesures radon
50	Gouvernement	Arrêté		2008-12-08	Radon lieux de travail
51	Gouvernement	Décret	NOR: DEVR1324351D	2013-12-31	PNGMDR 2013-2015
52		Circulaire		2009-07-22	Gestion des anciennes mines d'uranium
53		Circulaire		2008-11-17	Prise en charge de certains déchets radioactifs et de sites de pollution radioactive.

					Missions d'intérêt général de l'Andra
54	Gouvernement	Décret		1981-05-12	Décret UP3-A La Hague
55		Note	DGPR/SRT/MSNR/2013-52	2013	Actions nationales - Gestion des stériles miniers des anciennes mines d'uranium
56	ASN	Nomenclature	Rubrique modifiée par le Décret n° 2006-1454 du 24 novembre 2006)		Extraits de la nomenclature des installations classées pour la protection de l'environnement
57	ASN	Manuel	SMQ/DRC/QTL/CTR/ASN/N°000201	2013	Manuel de l'opération diagnostic radium
58		Guide	Guide N° 6 de l'ASN	2010	Mise à l'arrêt définitif, démantèlement et déclassement des installations nucléaires de base en France
59		Guide	Guide N° 14 de l'ASN projet	2010	Méthodologies d'assainissement complet acceptables dans les installations nucléaires de base en France
60	Gouvernement	Arrêté		2009-05-29	Transport de marchandises dangereuses pa voies terrestres (sans les annexes)
61	ASN Transports	Note		00/00/2013	Note de cadrage : Programme d'inspections 2014
62	ASN Transports	Guide	SMQ/DTS/QUI/INS/ASN/000046/2012	2014-03-03	Guide d'inspection transport routier de substances radioactives
63	ASN Transports			2007-11-10	Contrôle de la fabrication des emballages conformes à un modèle de colis agréé
64	ASN Sources	Guide	Guide DIT Instruction déclaration GERI + Annexe 3	2010-03-15	Délivrance d'un récepissé de déclaration d'utilisation d'un appareil électrique émettant des rayons X utilisés à des fins de radiodiagnostic vétérinaire ou à usage non médical
65	ASN Sources	Note	CODEP-DTS-2013-037373	2013-07-02	Note de cadrage : Propositions de la DTS pour l'orientation du programme d'inspection 2014
66	ASN Sources	Note	ASN/DIT/V3 Annexe Coche-coche V2 xls Annexe Matrice DIS/DIT V3 xls	2009-07-08	Enrichissement des missions des divisions : instruction des dossiers utilisateurs dans le domaine industriel, de recherche et vétérinaire (hors utilisation en vue de la distribution de sources de rayonnements ionisants)
67	ASN Sources	Guide	SMQ/DTS/QUI/INS/ASN/000024/2011	2011-11-10	Guide d'inspection gammagraphie : inspection en radiographie ou radioscopie industrielle

68	ASN Sources	Note	SMQ/DTS/QTL/ AUT/ASN/2014-01-29	2014	Modèle d'autorisation en nucleaire de proximite secteur industriel : détention/utilisation de radionucleides, d'appareils électriques émettant des rayonnements ionisants ou d'accélérateurs de particules
69	ASN Transports	,		2007-01-04	Support d'inspection des programmes d'assurance de la qualité applicables au transport de matières radioactives
70	ASN	PSP 2013-2015		2012-11-12	
71	ASN	DOO 2014		00/00/2013	
72	ASN	Manuel Qualité		2013-12-01	
73	ASN	Note Qualité	SMQ/100/ORG	2012-12-01	
74	ASN	Note Qualité	SMQ/100/ANI	2012-12-01	
75	ASN	Note Qualité	SMQ/100/REL	2013-12-01	
76	ASN	Note Qualité	SMQ/100/QA	2012-12-01	
77	ASN	Note Qualité	SMQ/100/REG	00/00/2008	
78	ASN	Note Qualité	SMQ/100/AUT	00/00/2009	
79	ASN	Note Qualité	SMQ/100/CON	00/00/2008	
80	ASN	Note Qualité	SMQ/100/INS	00/00/2007	
81	ASN	Note Qualité	ASN/INC/01	2009-01-31	Réaliser le retour d'expérience
82	ASN	Note Qualité	SMQ/100/SAN	2009-07-15	Mettre en œuvre les moyens de coercition et de sanction (hors actions inspecteurs du travail
83	ASN	Note Qualité	SMQ/100/EVA	00/00/2012	
84	ASN	Note Qualité	SMQ/100/URG	00/00/2012	
85	ASN	Note Qualité	SMQ/100/COM	2008-11-10	Information des publics
86	ASN	Note Qualité	SMQ/100/RH	00/00/2010	
87	ASN	Note Qualité	SMQ/100/MOY	00/00/2013	
88	ASN	Note Qualité	SMQ/100/INF	00/00/2010	
89	ASN/IRSN	Convention		00/00/2013	Convention ASN/IRSN
90	ASN/IRSN	Protocole		00/00/2014	Protocole ASN/IRSN 2014

APPENDIX VI - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

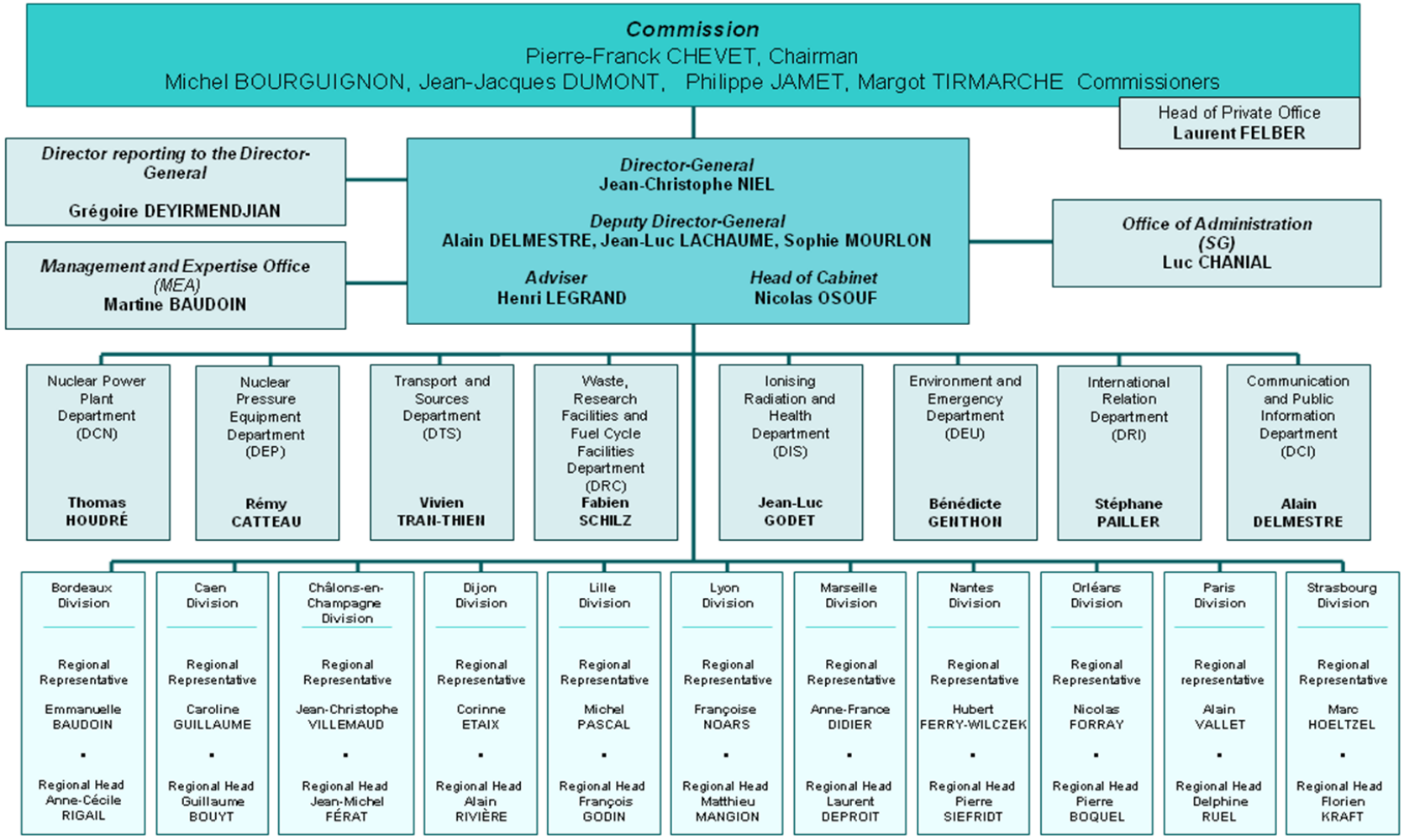
1.	**IAEA SAFETY STANDARDS SERIES No. SF-1** - Fundamental Safety Principles
2.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 1** - Governmental, Legal and Regulatory Framework for Safety
3.	**IAEA SAFETY STANDARDS SERIES No. GS-R-2** - Preparedness and Response for a Nuclear or Radiological Emergency
4.	**IAEA SAFETY STANDARDS SERIES No. GS-R-3** - The Management System for Facilities and Activities
5.	**IAEA SAFETY STANDARDS SERIES No. NS-R-1** – Safety of Nuclear Power Plants: Design
6.	**IAEA SAFETY STANDARDS SERIES No. NS-R-2** – Safety of Nuclear Power Plants: Operation
7.	**IAEA SAFETY STANDARDS SERIES No. NS-R-4** - Safety of Research Reactors
8.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.1-** Organization and Staffing of the Regulatory Body for Nuclear Facilities
9.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.2** - Review and Assessment of Nuclear Facilities by the Regulatory Body
10.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.3-** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
11.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.4** - Documentation for Use in Regulatory Nuclear Facilities
12.	**IAEA SAFETY STANDARDS SERIES No. GS-G-2.1** - Arrangements for Preparedness for a Nuclear or Radiological Emergency
13.	**IAEA SAFETY STANDARDS SERIES No.GS-G-3.1** - Application of the Management System for Facilities and Activities
14.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.2** - The Management System for Technical Services in Radiation Safety
15.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.3** - Assessment of Occupational Exposure Due to External Sources of Radiation
16.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.4** - Building Competence in Radiation Protection and the Safe Use of Radiation Sources
17.	**IAEA SAFETY STANDARDS SERIES No. NS-G-2.10** - Periodic Safety Review of Nuclear Power Plants Safety Guide

18. **IAEA SAFETY STANDARDS SERIES No. NS-G-211 -** A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide

19. **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).

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

APPENDIX VII ORGANIZATIONAL CHART - ASN



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