



**SYNTHESE DU RAPPORT DE LA MISSION D'EVALUATION IRRS  
REALISEE A L'ASN EN AVRIL 2009 PAR 12 EXPERTS INTERNATIONAUX  
COORDONNES PAR L'AIEA**

À la demande des autorités françaises, une équipe d'auditeurs internationaux composée de vingt-quatre experts s'est rendue à l'Autorité de sûreté nucléaire (ASN), l'Autorité française de contrôle de la sûreté nucléaire et de la radioprotection, en novembre 2006, afin de mener la première mission d'audit IRRS dite « full scope ». Le but de cette mission était, d'une part, d'examiner les dispositions mises en œuvre en France vis-à-vis des normes de sûreté de l'AIEA et, d'autre part, de partager des connaissances et de confronter les expériences entre l'ASN et les auditeurs de la mission IRRS en matière de contrôle de la sûreté nucléaire et la radioprotection.

En mars 2008, l'ASN a demandé une mission IRRS de suivi pour examiner les mesures prises pour répondre aux recommandations et aux suggestions présentées dans le rapport de la mission IRRS de 2006. Le champ d'intervention retenu pour cette mission IRRS de suivi portait sur l'ensemble des installations et des activités contrôlées par l'ASN comprenant des centrales nucléaires, des réacteurs de recherche, des installations du cycle du combustible, les activités médicales, industrielles et de recherche mettant en jeux des rayonnements ionisants, des installations de stockage de déchets, le démantèlement et la réhabilitation des sites et sols pollués, ainsi que la communication et l'information du public. Cette mission couvrait également l'application du Code de conduite relatif à la sûreté et à la sécurité des sources radioactives.

Cette mission de suivi a été menée du 29 mars au 3 avril 2009 par une équipe IRRS composée : de 12 experts en contrôle de la sûreté nucléaire et de la radioprotection provenant de onze Autorités de sûreté nucléaire étrangères et de quatre agents de l'AIEA. À l'issue de leur revue, ce groupe d'experts a reconnu que l'ASN avait pris des dispositions pour améliorer ses performances tout en faisant face à de nouveaux défis.

Préalablement à la mission, l'ASN a fourni à l'équipe d'experts un ensemble de documents soigneusement préparé comprenant une auto-évaluation de son organisation et de ses pratiques, le plan d'action mis en œuvre pour répondre aux conclusions de la mission de 2006 ainsi qu'un rapport portant sur son état d'avancement.

Au cours de cette mission, en complément à l'examen réalisé par les experts, des échanges ont eu lieu sur les sujets de fond portant sur : l'indépendance des Autorités de sûreté nucléaire, les relations entre l'ASN et son appui technique, l'Institut de radioprotection et de sûreté nucléaire (IRSN) et les incidents dans le domaine médical. La mission de suivi de l'IRRS incluait une série d'interviews et de discussions avec des agents de l'ASN ainsi que des observations sur le terrain d'actions réglementaires en complément de celles qui avaient été faites lors de la mission IRRS de 2006.

L'équipe d'auditeurs internationaux a conclu que l'ASN avait pris des initiatives en vue de répondre de manière systématique aux recommandations et aux suggestions qui leur avait été faites lors de la mission IRRS de 2006. Des progrès notables et de nombreuses améliorations ont été apportées dans de nombreux domaines grâce à la mise en œuvre d'un plan d'action prenant en compte l'ensemble des recommandations et des suggestions des experts. Les experts ont constaté que ce plan d'action était déjà largement mis en œuvre.

Les auditeurs ont par ailleurs noté que l'ASN, Autorité administrative indépendante de l'État français créée en 2006, était pleinement opérationnelle pour le contrôle de la sûreté nucléaire et de la radioprotection. L'ASN contrôle la sûreté nucléaire et la radioprotection dans le but de protéger les travailleurs, les patients, le public et l'environnement des risques associés aux activités nucléaires. Elle contribue à informer le public à propos des installations et des activités qu'elle contrôle.

L'équipe a confirmé les forces de l'ASN telles qu'elles avaient été identifiées par la mission de 2006, en particulier son statut d'organisme de contrôle du nucléaire mature et transparent, sa politique d'information et de communication avec le public, son rôle international actif, tout particulièrement avec l'AIEA, et son mécanisme d'habilitation des inspecteurs clair et efficace.

Au cours de la mission IRRS de suivi, de bonnes pratiques supplémentaires ont été identifiées, notamment :

- son rôle significatif dans le domaine de la promotion et de l'harmonisation de la sûreté nucléaire au niveau européen (directive européenne) et sa pro-activité au niveau international ;
- ses efforts importants pour éviter d'être isolée vis-à-vis de ses parties prenantes en établissant des conventions et des protocoles avec des administrations et des organismes locaux, nationaux et internationaux ;
- la prise en compte de considérations réglementaires et de contrôles dans un souci d'anticipation à long terme vis-à-vis de la sûreté nucléaire en France et à l'étranger ;
- la mise en place d'un projet, auquel participent des experts de l'ASN et de l'IRSN, pour développer la réglementation en consultant les parties prenantes de l'ASN notamment les exploitants des installations et des activités nucléaires ;
- le développement d'une échelle ASN-SFRO qui permet de classer les événements qui se produisent dans le domaine de la radiothérapie en fonction de leur conséquence ;
- la mise en ligne sur le site [www.asn.fr](http://www.asn.fr) des lettres transmises aux centres de radiothérapie après inspection, une disposition qui constitue un puissant levier pour faire respecter la réglementation ;
- les dispositions nationales prises avec le ministère en charge de l'environnement pour développer une approche cohérente du traitement des sites contaminés, indépendamment de l'organisme responsable du contrôle de ces sites.

Le rapport de 2006 incluait des recommandations et des suggestions pour consolider le cadre réglementaire de la sûreté et sa mise en œuvre. On citera, d'une part, la promulgation en 2006 de la loi relative à la transparence et à la sécurité en matière nucléaire (TSN) et, d'autre part, les actions mises en œuvre pour renforcer la position de l'ASN vis-à-vis de l'IRSN, son appui technique, en tant que client intelligent pour les expertises qu'elle lui commande.

Au cours de la mission de suivi, les experts internationaux ont souligné l'action de l'ASN qui a permis de solder la majeure partie des recommandations et des suggestions émises en 2006.

Le rapport de la mission de 2009 identifie quelques nouvelles recommandations et suggestions pour renforcer le contrôle en France et pour encourager l'amélioration continue de l'activité de l'ASN. En particulier, il est nécessaire que l'ASN :

- développe ses compétences internes notamment pour consolider sa capacité à évaluer ses besoins en termes d'expertise et d'appui technique et la qualité des expertises qui lui sont remises ;

- améliore sa gestion budgétaire pour être mieux à même d'adapter ses actions de recherche à ses besoins liés au contrôle de la sûreté nucléaire et de radioprotection ;
- audite l'IRSN en tant que commanditaire majeur de l'Institut ;
- prenne en charge rapidement le contrôle de la sûreté des sources radioactives dès l'obtention de l'accord du Premier Ministre.

L'équipe souligne également la qualité du travail déjà mené par l'ASN dans de nombreux domaines dans lesquels les recommandations de 2006 n'ont pas encore été complètement remplies mais où des progrès considérables ont été faits. Par exemple, l'ASN a fait des progrès considérables dans la mise en place des exigences et des pouvoirs issus de la loi TSN de 2006 et a initié un programme permanent pour le développement des ordres, des décisions de l'ASN, et des notes supplémentaires de l'ASN, qui sera en charge de couvrir l'ensemble des activités de contrôle de l'ASN.

En accord avec la mission IRRS de 2006, un fort consensus est apparu au sein de la mission de revue sur le fait que la France et les États membres de l'AIEA ont amélioré le contrôle de la sûreté nucléaire et de la radioprotection à travers le monde grâce aux missions IRRS coordonnées l'AIEA. C'est la première fois qu'une mission de revue IRRS complète a fait l'objet d'un audit de suivi. Cet exemple donnera sans nul doute une impulsion considérable au déploiement de ce type de mission à travers le monde ce qui permettra de renforcer la sûreté nucléaire et la radioprotection en améliorant les organisations des Autorités de sûreté nucléaire et leurs pratiques de contrôle.



**IAEA**

International Atomic Energy Agency

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

Paris, France

*29 March to 3 April 2009*

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



# **INTEGRATED REGULATORY REVIEW SERVICE**

## **IRRS**

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish or adopt, in consultation and, where appropriate, in collaboration with competent organizations, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning peaceful nuclear and radiation activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. As part of its providing for the application of safety standards, the IAEA provides Safety Review and Appraisal Services, at the request of Member States, which are directly based on its Safety Standards.

In the regulatory framework and activities of the regulatory bodies, the IAEA has been offering, for many years, several peer review and appraisal services. These include: (a) the International Regulatory Review Team (IRRT) programme that provides advice and assistance to Member States to strengthen and enhance the effectiveness of their legal and governmental infrastructure for nuclear safety; (b) the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) that assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources; (c) the Transport Safety Appraisal Service (TranSAS) that appraises the implementation of the IAEA's Transport Regulations; and (d) the Emergency Preparedness Review (EPREV) that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

The IAEA recognized that these services and appraisals had many areas in common, particularly concerning the requirements on a State to establish a comprehensive regulatory framework within its legal and governmental infrastructure and on a State's regulatory activities. Consequently, the IAEA's Department of Nuclear Safety and Security has developed an integrated approach to the conduct of missions on legal and governmental infrastructure to improve their efficiency, effectiveness and consistency and to provide greater flexibility in defining the scope of the review, taking into account the regulatory technical and policy issues.

The new IAEA peer review and appraisal service is called the Integrated Regulatory Review Service (IRRS). The IRRS is intended to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste and transport safety, whilst recognizing the ultimate responsibility of each State to ensure the safety of nuclear facilities, the protection against ionizing radiation, the safety and security of radioactive sources, the safe management of radioactive waste, and the safe transport of radioactive material. The IRRS is carried out by comparisons against IAEA regulatory safety standards with consideration of regulatory technical and policy issues.

The new regulatory service is structured in modules that cover general requirements for the establishment an effective regulatory framework, regulatory activities and management systems for the regulation and control in nuclear safety, radiation safety, waste safety, transport safety, emergency preparedness and response and security. The aim is to make the IAEA services more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs and priorities of the Member State. The IRRS is neither

an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, considering the regulatory technical and policy issues, and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

- a balance between technical and policy discussions among senior regulators;
- sharing of regulatory experiences;
- harmonization of the regulatory approaches among Member States; and
- mutual learning opportunities among regulators.

Regulatory technical and policy discussions that are conducted during IRRS missions take into account the newly identified issues coming from the self-assessment made by the host organization, visits to installations to observe inspections and interviews with the counterparts.

Other legally non-binding instruments can also be included upon request of the Member States, such as the Code of Conduct (CoC) on the Safety and Security of Radioactive Sources, which was adopted by the IAEA Board of Governors in 2004 and for which more than eighty Member States have written to the Director General of the IAEA committing themselves to implementing its guidance, and the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in 2005.

The IRRS concept was developed at the IAEA Department of Nuclear Safety and Security and then discussed at the 3<sup>rd</sup> review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2005. The meeting acknowledged the importance of the IAEA regulatory peer reviews now recognized as a good opportunity to exchange professional experience and to share lessons learned and good practices. The self-assessment performed prior to the IAEA peer review mission is an opportunity for Member States to assess their regulatory practices against the IAEA safety standards. These IAEA peer review benefits were further discussed at the International Conference on 'Effective Nuclear Regulatory Systems' in Moscow in 2006, at which note was taken of the value of IRRS support for the development of the global nuclear safety regime, by providing for the sharing of good regulatory practices and policies for the development and harmonization of safety standards, and by supporting the application of the continuous improvement process. All findings coming from the Convention on Nuclear Safety review meetings and from the Moscow conference are inputs for the IRRS to consider when reviewing the regulatory technical and policy issues.

In addition, the results of the IRRS missions will also be used as effective feedback for the improvement of existing safety standards and guidance and the development of new ones, and to establish a knowledge base in the context of an integrated safety approach. Through the IRRS, the IAEA assists its Member States in strengthening an effective and sustainable national regulatory infrastructure thus contributing towards achieving a strong and effective global nuclear safety and security regime.

The Global Nuclear Safety Regime has emerged over the last ten years, with international legal instruments such as safety Conventions and Codes of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA safety standards. The IAEA will continue to support the promotion of the safety Conventions and Codes of Conduct, as well as the application of the IAEA safety standards in order to prevent serious accidents and continuously improve global levels of safety.

# REPORT

INTERNATIONAL REGULATORY REVIEW SERVICE (IRRS)

FOLLOW-UP

REPORT TO  
THE GOVERNMENT OF FRANCE

Paris, France  
*29 March to 3 April 2009*



# REPORT

## INTERNATIONAL REGULATORY REVIEW SERVICE (IRRS)

### FOLLOW-UP

### REPORT TO

### THE GOVERNMENT OF FRANCE

Paris, France

*29 March to 3 April 2009*

**Mission date:** 29 March to 3 April 2009

**Regulatory body:** ASN

**Location:** ASN Headquarters, Paris, France

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

**Organized by:** IAEA

**IAEA Review Team:** CRESWELL, Len (Team Leader, UK)  
MCEWAN, Andrew (Deputy Team Leader, New Zealand)  
ABE, Kiyoharu (Japan)  
BOGER, Bruce (USA)  
ELDER, Peter (Canada)  
LARSSON, Carl-Magnus (Sweden)  
LINSENMAIER, Bernd (Switzerland)  
SAMAIN, Jean Paul (Belgium)  
VARJORANTA, Tero (Finland)  
ZARZUELA, Javier (Spain)  
GABRIEL, Sandra (USA)  
KUMAR, Selva (Australia)  
CARUSO, Gustavo (IAEA/NSNI, Team Coordinator)  
REBER, Eric (IAEA/NSRW, Deputy Team Coordinator)  
KOBAIN, Marlene (IAEA Administrative Support)

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## **FOREWORD**

by Mohamed ElBaradei  
Director General

The General Conference Resolution of September 2006 related to the measures to strengthen international cooperation in nuclear, radiation and transport safety and waste management: “Recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat’s new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS.”

At my opening speech of the fiftieth regular session of the General Conference in 2006, I stated that: “The Agency’s safety review services use the IAEA Safety Standards as a reference point, and play an important part in evaluating their effectiveness. This year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS). This new service combines a number of previous services, on topics ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security. The IRRS approach considers international regulatory issues and trends, and provides a balance between technical and policy discussions among senior regulators, to harmonize regulatory approaches and create mutual learning opportunities among regulators.”

**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 authorities of France, an international team of 24 experts visited the Autorité de Sûreté Nucléaire (ASN), the French regulatory authority for nuclear and radiation safety, in November 2006 to conduct the first full scope Integrated Regulatory Review Service (IRRS) mission. The purpose of the mission was to undertake a peer review of the regulatory body of France against the IAEA Safety Standards and to exchange information and experience on safety regulation.

In March 2008 the Government authorities of France requested a follow-up mission to review the measures undertaken following the recommendations and suggestions presented in the report of the November 2006 IRRS mission. The scope of the IRRS follow-up mission covered the regulatory aspects of the facilities and practices regulated by ASN, nuclear power plants, research reactors, fuel cycle facilities, medical practices with further review of radiotherapy, industrial and research activities, waste facilities, decommissioning, remediation, public information and communication and, in addition, it was also extended to cover the application of the Code of Conduct of Safety and Security of Radioactive Sources.

The review was conducted from March 29<sup>th</sup> to April 3<sup>rd</sup> 2009 by an IRRS team consisting of 12 senior regulatory experts from 11 Member States, two staff members from the IAEA, one IAEA observer and an IAEA administrative assistant. During the review the team recognized that ASN has taken a number of initiatives to improve its effectiveness and efficiency and that ASN faces new challenges.

ASN supplied a package of documentation and a well prepared self-assessment, in advance of the mission, including a status report and an action plan to improve its regulatory effectiveness.

Both regulatory technical and policy issues were addressed. The policy issues discussed were: regulatory independence, the relationship between ASN and IRSN and medical issues. The IRRS follow-up mission included a series of interviews and discussions with key personnel at ASN and regulatory observations in the field in addition to those carried out during the main mission to provide additional insight to the review.

The team concluded that ASN has taken initiatives to address, in a systematic manner, all the recommendations and suggestions from the 2006 IRRS mission. There has been significant progress and many improvements have been carried out in many areas. ASN established an action plan for all those recommendations and suggestions, which ASN has the full responsibility to address. ASN is well advanced in its implementation of this plan.

The IRRS review team saw that the new ASN Commission, created in 2006 as an independent administrative authority within the State of France, is now established and provides strategic leadership in the regulation of nuclear and radiation safety. ASN regulates nuclear safety and radiation protection in order to protect workers, patients, the public and the environment from risks associated with nuclear activities. It contributes to informing the public about the facilities and activities it regulates.

The team confirmed ASN's strengths, as identified during the IRRS 2006 mission and in particular: being a mature and transparent nuclear regulator, having a strong policy for informing and communicating with the public, maintaining an active international role, particularly at the IAEA, and executing a well-developed and comprehensive inspector accreditation programme.

During the IRRS follow-up mission additional good practices were identified which include:

- ASN plays a significant part in promoting the harmonization of safety at the European level (European directive), and is proactive in leading activities at the international level;

- ASN makes strong efforts to avoid being isolated among relevant stakeholders, establishing conventions and protocols with local, national and international stakeholders;
- ASN takes into account long term considerations and regulatory positions in order to ensure long term safety in France and abroad;
- ASN has created an organization specifically devoted to developing standards, which involves ASN and IRSN experts; it consults the operating organizations of the nuclear facilities and activities it regulates and has in place a system to ensure consistency, completeness and the state of the art of the standards produced;
- ASN has developed the ASN-SFRO severity scale as a tool to convey understanding of the significance of reported events in radiotherapy and the placement of radiotherapy inspection reports on the ASN website is a powerful enforcement tool;
- ASN has established a formal relationship with the ministry responsible for the environment allowing the development of a national approach to the treatment of contaminated sites, irrespective of who has the regulatory responsibility for the sites.

The 2006 report included recommendations or suggestions where improvements were necessary or desirable to further enhance the legal and regulatory framework for safety, in particular: implementation of the new Transparency and Nuclear Safety (TSN) 2006 Act, and the need to continue to develop and sustain the technical expertise to ensure the products and services provided by IRSN are technically adequate, i.e. an ‘intelligent customer’ capability.

During the follow-up mission the IRRS team found that a great many of the recommendations and suggestions of the 2006 report had been fully addressed and therefore could be considered closed. ASN should be strongly commended for this.

This report also includes a number of new recommendations and suggestions to further strengthen the regulatory body in France and to support the observed continuous improvement. The IRRS team considers that it is important that ASN should:

- Develop its core competence in all areas of review and assessment in order to determine and oversee the technical support needed for regulatory purposes;
- Increase budgetary flexibility and independence in order to define and carry out the review and assessment and have research needed for regulatory purposes;
- Audit IRSN’s review and assessment functions against ASN’s management system requirements;
- Implement its proposal for the regulation of the security of radioactive sources expeditiously once it receives approval for the proposal from the Prime Minister’s office.

The team considers that ASN should also be commended for the work it has done in many areas where the recommendations from 2006 have not yet been fully closed out but where considerable progress has been made. For example, ASN has made considerable progress in the implementation of the requirements and powers given to it by the TSN 2006 Act and has initiated a continuing programme for the development of orders, ASN decisions, and additional ASN notes, which is planned to cover the full range of ASN regulated activities.

As with the 2006 mission, there was a strong consensus among the review team that France and IAEA Member States have been improving the regulation of nuclear and radiation safety worldwide through IAEA regulatory review missions. This is the first time an IRRS full scope mission has been followed by a full scope follow-up mission, and it is considered that this will give considerable impetus to the series of IRRS missions for enhancing nuclear and radiation safety worldwide through continuous improvement of regulatory organizations and practices.

## I. INTRODUCTION

### BACKGROUND

In 2006 at the request of the French Government Authorities, an IAEA team of twenty four experts consisting of experts from sixteen Member States among them two observers, and six staff members from the IAEA and an IAEA administrative assistant visited the Autorité De Sûreté Nucléaire (ASN) in November 2006 to conduct a full scope Integrated Regulatory Review Service (IRRS). In May 2006 a preparatory mission had been carried out at ASN headquarters, Paris, to discuss the objective and purpose of the review as well as its scope in connection with all aspects of the new French regulatory authority. The purpose of the 2006 mission was to conduct a review of the entire French regulatory framework and the regulatory activities in all regulated facilities and practices, to review the effectiveness of ASN and to exchange information and experience in the regulation of the areas considered by IRRS. The areas reviewed were: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; emergency preparedness; radioactive waste management; the management system; transport (as a follow-up to an IAEA Transport Safety Appraisal Service – TranSAS); and public information and communication. In addition, the regulatory technical and policy issues considered in this review provide a greater understanding of the regulatory issues that may have international implications and assist in addressing specific technical issues relevant to the regulation of nuclear, radiation, radioactive waste and transport safety. Regulatory technical and policy issues were identified after reviewing a broad spectrum of information including insights resulting from the conclusions of the Nuclear Safety Convention review meetings, international conferences and forums and previous IAEA safety review services. In 2006 the IRRS activities took place mainly at the ASN headquarters, Bourgoin, and its offices at Fontenay-aux-Roses, ASN Division of Paris, Ile de France., ASN Division of Nantes, Pays de Loire, ASN Division of Dijon, Bourgogne, ASN Division of Châlons-en-Champagne, Champagne-Ardennes, ASN Division of Caen, Basse-Normandie and ASN Division of Lyon, Rhone-Alpes. Site visits for facilities, activities and practices took place in several areas; visits were made to nuclear power plants, research reactors, fuel cycle facilities, medical activities and practices, industrial sources and waste disposal facilities.

### FOLLOW-UP MISSION

In March 2008 the Government authorities of France requested a follow-up mission to review the measures undertaken following the recommendations and suggestions presented in the report of the November 2006 IRRS mission. The scope of the IRRS follow-up mission covered the regulatory aspects of the facilities and practices regulated by ASN, nuclear power plants, research reactors, fuel cycle facilities, medical practices with further review of radiotherapy, industrial and research activities, waste facilities, decommissioning, remediation, public information and communication and, in addition, it was also extended to cover the Code of Conduct of Safety and Security of Radioactive Sources.

The review was conducted from March 29<sup>th</sup> to April 3<sup>rd</sup> 2009 by an IAEA team consisted of 11 senior regulatory experts from 11 Member States, two staff members from the IAEA, one IAEA observer and an IAEA administrative assistant.

## II. OBJECTIVE AND SCOPE

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

This mission covered all areas included in the main IRRS mission in 2006. The IRRS mission was structured in order to take into account the progress in implementing improvements resulting from IRRS 2006 mission and reviewing the areas of significant change since the last mission.

As stated in the main mission the key objectives of this mission were to enhance safety by:

- ✓ Providing the host country (regulatory body and governmental authorities) with a review of their nuclear and radiation safety regulatory technical and policy issues;
- ✓ Providing the host country with an objective evaluation of their nuclear and radiation safety regulatory practices with respect to international safety standards;
- ✓ Contributing to the harmonization of regulatory approaches among Member States;
- ✓ Promoting sharing of experience and exchange of lessons learnt;
- ✓ Providing key staff in the host country with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- ✓ Providing the host country with recommendations and suggestions for improvement;
- ✓ Providing other States with information regarding good practices identified in the course of the review;
- ✓ Providing reviewers from States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field; and
- ✓ Providing the host country through completion of the IRRS questionnaire with an opportunity for self-assessment of its activities against international safety standards.

### III. BASIS FOR THE REVIEW

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

The preparatory work for the mission was carried out by the IRRS IAEA Coordinator Mr. Gustavo Caruso, SH-NSNI/ IAEA, by the ASN Liaison Officer Mr. Jean-René Jubin, Deputy Head of Expertise and Management Office and by the IRRS Deputy Coordinator Mr. Eric Reber, NSRW/IAEA.

There was a preparatory meeting organized on November, 14<sup>th</sup> with the participation of the appointed IRRS team leader also for 2006, Mr. Len Creswell, Deputy Chief Inspector NSD/HSE from United Kingdom, the team coordinator and the deputy team coordinator. The preparatory meeting was opened by Mr. Andre-Claude Lacoste, Chairman, ASN, who also provided an organizational overview. Mr. J-C Niel, Director General, ASN, described their action plan for addressing the findings from the 2006 IRRS mission.

To provide a structure for the planned follow-up mission, it was agreed that the implementation of the ASN action plan would be reviewed with regard to the following categories: regulations, management system, IRSN relationship, radiotherapy, human resources (ASN), enforcement, experience feedback, waste management and research for regulatory purposes. It was also agreed that the issue of radiotherapy will be given special emphasis with particular attention paid to relevant regulations, regulatory guides, and inspection and enforcement activities. In addition to the areas described above, it was agreed that a new area would be reviewed, that being the efforts of ASN with regard to the principles of the Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct).

Discussions were held regarding two policy issues that were proposed to be included in the follow-up mission: Independence of regulatory bodies (towards governmental, financial issues and “de jure” versus “de facto”) and nuclear medical issues. On-site reviews, visits, advance reference material and main agenda items were discussed. The ASN’s Chairman closed the meeting.

In accordance with the request from ASN and taking into account the scope of the follow-up mission as indicated above, it was agreed that the IAEA review team would be comprised of 12 IAEA external experts from 11 Member States, Australia, Belgium, Canada, Finland, Japan, New Zealand, Spain, Sweden, Switzerland, United Kingdom, United States, 2 IAEA Staff, 1 IAEA observer and 1 IAEA administrative assistant (see Appendix I). The working areas and the ASN counterparts were distributed according to Appendix III).

During the preparatory period all documents of the advance reference material (ARM) were sent electronically by ASN to the IAEA and distributed to the experts. All details and organizational aspects were defined with the ASN President Mr. Lacoste, the ASN Director General Mr. Niel, the nominated ASN Liaison Officer Mr. Jean-René Jubin, Deputy Head of Expertise and Management Office, and the IAEA staff.

A significant amount of work was carried out by the reviewers and by the IAEA staff before the review in order to prepare the initial impressions about the ARM, to review the self-assessment sent by ASN, to prepare for the interviews and additional observations and to identify additional relevant material necessary to review during the mission.

An entrance team meeting was conducted on Sunday 29<sup>th</sup> November in the ASN headquarters by Mrs Comets and Mr Gouze (ASN Commissioners), ASN Director General, the IRRS Team Leader and the IRRS IAEA Coordinator to discuss the specifics of the mission and main aspect from the IRRS 2006, to clarify the basis for the review, background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. The Liaison Officer presented the logistics aspects and additional aspect of the follow-up mission organization. ASN Management presented an overview of the ASN’ action plan implementation on the key areas: Management system (Mr Mochel), Human resources (Mr Chanial), IRSN relationship

(Mrs Baudoin), Regulation on nuclear safety (Mr Gupta, Mr Mochel), Sanction and enforcement (Mr Lachaume), Experience feedback (Mr Lachaume), Waste management (Mr Rieu), Radiotherapy (Mr Krembel), Research for regulatory purpose (Mrs Baudoin), Overview on ASN self-assessment against the Code of Conduct (Security of Radioactive Sources) (Mr Landier), Action plan presentation and discussion (Mr Landier, Experts).

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

The main reference documents provided by ASN for the review mission are indicated in Appendix IV. The most relevant IAEA Safety Standards and other reference documents used for the review are indicated in Appendix V.

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

The entrance meeting was held on Monday 30 March with the participation of all ASN Commissioners Mr. Andre-Claude Lacoste, Chairman of ASN, Mr. Bourguignon, Mr. Sanson, Mr. Gouze and Ms. Comets, ASN Director General, ASN Executive Board, ASN regional representatives, ASN Counterparts, Liaison Officer, Mr Lelièvre (ASN Division of Paris), Mr P Deschamps (IRSN) and Mr Billarand (IRSN). Opening remarks were made by Mr. Lacoste, Mr. Creswell and Mr. Caruso.

During the mission, a systematic review was conducted for all the areas from the IRRS 2006 with the objective to review the ASN's progress in response to IRRS mission recommendations or suggestions as well as of identifying new good practices. The review was conducted through meetings, interviews and discussions with ASN personnel, assessment of the ARM, and direct observations regarding the national practices and activities, particularly in the context of inspections.

The team performed its activities based on the Mission Programme given in Appendix II.

The exit meeting was held on Friday 3rd April with the ASN Commissioners, ASN Director General, ASN Executive Board, ASN Counterparts, Liaison Officer, Mr Lelièvre (ASN Division of Paris), Mr Billarand (IRSN) and Department Heads. The main conclusions of the IRRS follow-up mission were presented by the IRRS Team Leader, and closing remarks were made by Mr. Tomihiro Taniguchi, IAEA Deputy Director General and by Mr. Lacoste. The draft technical notes were handed over to ASN at the end of the meeting.

## 1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

### 1.1 PRINCIPAL LAWS OR OTHER LEGAL PROVISIONS

#### Recommendations and Suggestions from IRRS 2006 Report

##### RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- R1 Recommendation:** In order to fully clarify and enhance its independent status, and put into place the new enforcement powers, ASN should as soon as practicable fully implement the requirements and the powers given to it by the new TSN 2006 Act through elaboration and implementation of the necessary Decrees and Orders.
- R2 Recommendation:** Although ANDRA has some responsibility in this area, ASN should continue its work to clarify and formalize the arrangements to ensure safety e.g. for “orphan” sources.
- R3 Recommendation:** ASN should consider development of its input into and formal monitoring of research and development in nuclear and radiation safety.
- S1 Suggestion:** ASN should interact with the administrative authority which controls the funds for radioactive waste management and decommissioning to make technical competence available and to provide assessments of feasibility and other aspects of plans that can underpin decisions on financing made by the administrative authority.
- R4 Recommendation:** The clarification of interaction between the Ministry of Labour and ASN concerning the radiation protection of workers should be carried out.

#### Changes since the IRRS 2006 Mission

**Recommendation 1:** ASN has made considerable progress in the implementation of the requirements and powers given to it by the TSN 2006 Act. Decree 2007-831 of May 11, 2007, established the requirements for inspectors and Decree 2007-1557 of November 2, 2007, established, among others, penal provisions for non-compliances. Furthermore, ASN drew up procedures and decision-making tools regarding the position to be adopted by the inspectors when infringements are identified. ASN note ASN/SAN/02 describes a graduated approach for enforcement actions, including the smallest deviations. The approach considers the observed risk for people and the environment and takes into account factors specific to the licensee (history, behavior, repeated nature of the problem), contextual factors, and the nature of the infringements observed (regulations, standards, internal procedures, etc.). Infringements punishable by penal sanctions are transmitted formally to the Public Prosecutor’s Office. Several enforcement actions have taken place under the new enforcement policy. An order and several ASN decisions are under development to more fully describe licensee responsibilities and additional ASN notes are planned to cover the full range of ASN enforcement powers.

#### Findings from the 2009 Follow-up IRRS Mission

**Recommendation 1 is open:** pending completion of ASN activities related to the development of the order, ASN decisions, and additional ASN notes planned to cover the full range of ASN enforcement powers.

**Recommendation 2 is closed on the basis of progress and confidence:** –EU Directive 2003/122/EURATOM on the Control of High Activity Sealed Radioactive Sources and Orphan Sources requires Member States to implement a system of supplier responsibility to manage orphaned sources. This requirement has been implemented in France’s domestic law under Article L1333-7 of the Public Health Code, Chapter III – Ionising Radiation, which requires suppliers to

provide a 'financial warranty' for the management of end-of-life and orphaned sources. The detailed requirements are spelled out in Articles R1333-53 and R1333-54 of the Health Code, under which suppliers cannot get a licence to import or export a radioactive source without presenting a financial warranty for the end of life management of the radioactive source. Since the 1990s, suppliers in France of sealed radioactive sources have been providing the required financial warranty under one of two schemes.

One scheme, which is provided by ANDRA, involves paying for the end of life disposal of the source in advance based on an estimate of the cost of disposal ten years later. In practice, this is the more expensive option. However, almost the full price of disposal is actually refunded to the supplier if the supplier takes back the source from the user for end-of-life management. The other scheme, which costs less, is administered by a 'Resource Association' formed by suppliers. The Resource Association would, for a smaller but non-refundable fee, undertake to dispose of any orphaned source. Orphaned sources for which no supplier can be identified had in the past been managed by ANDRA as a public service commitment, but since 2006 ANDRA has received funding from the Government. In order to implement Recommendation 2, ASN is now preparing a Ministerial Order to formalize the two end of life management schemes described above to minimize the risk of the 'Resource Association' being dissolved and also to give ASN the power to require the schemes to adjust their fees.

**Recommendation 3 is closed:** ASN should consider development of its input into and formal monitoring of research and development in nuclear and radiation safety.

This topic is clearly linked with the preceding one. IRSN remains the essential resource for expertise in the French context. We have to consider that IRSN is an organization of about 1800 people wherein about 500 are working for the needs of ASN (Safety expertise on various fields). This comparison shows, more than clearly, which importance the expertise of IRSN represents for ASN.

The first issue for ASN was to be aware of the ongoing actions in their fields of interest, with the aim to identify the possible support of expertise. An inventory has been established.

The second issue relate to the financial aspects. ASN has no direct way to determine the IRSN budget dedicated to the research supporting the needed expertise. Very recently the situation had been (slightly) improved by the creation of a committee which aim is orienting the projects of research (COR = Comité d'orientation de la recherché). This committee works in the framework of the Ministry (MEEDAT = Ministère de l'Ecologie, de l'Energie, du développement durable et de l'Aménagement du territoire) and coordinate all the research projects subsidied by the MEEDAT. As a participant (between others) ASN is now able to advise about the allocation of money to IRSN research projects.

COR seems to be a good tool to give ASN some (sufficient?) influence on the devolution of the money to IRSN, with the aim to develop the needed expertise and tools dedicated to safety reviews.

It is too premature to assess the effectivity of this new committee with respect to the needs of ASN.

(Regarding Recommendation 1) ASN has made considerable progress in the implementation of the requirements and powers given to it by the TSN 2006 Act. Decree 2007-831 of May 11, 2007, established the requirements for inspectors and Decree 2007 of 2007-1557 of November 2, 2007, established penal provisions for non-compliances. Furthermore, ASN drew up procedures and decision-making tools regarding the position to be adopted by the inspectors when infringements are identified. ASN note ASN/SAN/02 describes a graduated approach for enforcement actions, including the smallest deviations. The approach considers the observed risk for people and the environment and takes into account factors specific to the licensee (history, behavior, repeated nature of the problem), contextual factors, and the nature of the infringements observed (regulations, standards, internal procedures, etc.). Infringements punishable by penal sanctions are

transmitted formally to the Public Prosecutor's Office. Several enforcement actions have taken place under the new enforcement policy. Orders are under development to more fully describe licensee responsibilities and additional ASN notes are planned to cover the full range of ASN enforcement powers.

**Recommendation 4 is closed:** ASN provided to the IRRS team a copy of a November 2001 circular clarifying the responsibilities of the Ministry of Labor and ASN with regard to protection of workers. ASN also provided a copy of a July 2008 convention between the agencies, accompanied by a protocol. This recommendation has been completed.

## **1.2 AUTHORITY OF THE REGULATORY BODY**

### ***Recommendations and Suggestions from IRRS 2006 Report***

*In this part of the document there were no recommendations or suggestions.*

### ***Changes since the IRRS 2006 Mission***

ASN provided to the IRRS team a copy of a November 2007 circular clarifying the responsibilities of the Ministry of Labor and ASN with regard to radiation protection of workers. ASN also provided a copy of a July 2008 convention between the agencies, accompanied by a protocol.

## Policy Issues of Regulatory Independence

### Background

Six elements of regulatory independence to ensure its credibility and its effectiveness have been identified: political, legal, financial, competence, information of the public, international

#### Political

There is a clear distinction between ASN, which cooperates only with foreign nuclear safety Authorities and AFNI – INFA (international nuclear French agency), in charge of promoting French expertise abroad.

ASN, which already was independent de facto, has been made independent de jure in 2006 by the TSN Act which gave it the status of an “independent administrative authority”:

- “Independent” since it is not subject to political, financial or industrial pressure/lobbying;
- “Administrative” since it is a part of the State;
- “Authority” since it is empowered to make and enforce decisions.

The TSN Act of 13<sup>th</sup> June 2006 states (art. 13): “The members of the college exercise their duties entirely impartially without receiving any instruction from the Government or from any other person or institution”.

ASN gives priority to reporting to the Parliament as opposed to the Government.

The ASN Commission embodies independence (collective decision making process between members with different profiles and experiences). Commissioners have a 6 year-mandate non-renewable and cannot be dismissed; duty of "ungratefulness" towards nominating authorities. Moreover, there are mandatory statements of interest, including financial ones for commissioners when starting their mandate.

The Commission is paid for saying "no", in fact for its ability to say “no”. For instance, before it became an independent administrative authority, it would have been difficult for ASN to order the closure of radiotherapy units.

For an independent Authority, the long-term thinking and action for the protection of the population is at the same level of priority than the reactive decision making in case of emergency, hence the ASN public statement on the provision of nuclear plants in countries embarking on nuclear power countries.

The Authority must only be concerned with nuclear safety and radioactive protection matters and not with other factors, such as economical concerns, as a Minister would be.

#### Legal

The legislative and regulatory framework has been extensively complemented since the issuance of the TSN Act of 13 June 2006.

Almost all the decisions either about BNI or medical fields are made by ASN

ASN issues the commissioning license and it decides on the delicensing. In case of emergency, it may order the temporary shutdown of the facility. It imposes technical regulations relevant to the construction, operation and decommissioning of BNIs.

A very small number of decisions are made by the Prime Minister (but still proposed by ASN) such as creation of a BNI, shutdown and decommissioning (about ten decisions a year maximum).

Enforcement actions and penalties have been used in the past but these are not frequently resorted to. There is no hierarchical appeal (such as an appeal before a Minister); however ASN decisions may be appealed before the highest administrative court (*Conseil d'Etat*). The Government may

override an ASN decision by making the Parliament modify the legislative repartition between ASN and the Government.

### Financial

The ASN budget is decided by the Parliament and subject to the financial public control court (*Cour des comptes*).

ASN has proposed to aggregate the different components of its budget to make it clearer and more manageable. It is working on a project to gain financial autonomy as it is the case for some other independent administrative authorities.

Considering the increase in ASN missions (international cooperation, new NPPs), ASN needs more flexibility to hire specialized staff but the present rules are too strict.

### Competence

Competence is one of the core values of ASN. In addition to its in-house competence and technical skills ASN obtains expertise from its Technical Support Organization (TSO) IRSN.

This area is further discussed in the policy discussion on “the relationship between ASN and IRSN”

### Information of the public

ASN emphasizes the importance of dispatching information to the Public as illustrated by the following examples: ASN publishes, including on its website, all the decisions and official opinions, as well as inspection follow-up letters on nuclear safety and radiotherapy (4,500 until now). In addition ASN makes its annual report available both in French and English; (new English version of the website has been established). Finally, ASN issues information statements, press releases; and regular press conferences reports.

ASN also publishes the Standard advisory committee’s opinions on the basis of which ASN decisions are made.

### International

The chairman of ASN represents France *de facto* in international forums; and is a member of the French delegation, with other commissioners (such as CNS, JC).

ASN believes that, for a nuclear safety Authority, independence enables to:

- make impartial decisions;
- make legally and technically strong decisions;
- have in mind only nuclear safety and radioactive protection matters;
- think ahead;
- inform the public in a clear and credible way.

The actions promoted by ASN to enhance its independence include:

- more frequent public statements
- broader use of all means of enforcement and penalties
- reinforcement of financial autonomy
- strengthening of institutional cooperation with IRSN including identifying priorities on major issues
- development of expertise from other entities
- development of international cooperation to increase independence.

## **Discussion**

The Parliament, while creating ASN as an independent administrative authority, left to the Government two main responsibilities, authorization for creation of BNIs and decommissioning/dismantling of BNIs, since these are considered political decisions. However in case of emergency or high risk situations, ASN can decide to suspend the operation as long as it deems it necessary.

ASN may decide the shutdown of BNIs well in advance, as illustrated by Phénix shutdown decision.

A fundamental question raised during the discussion regarded justification principle, and the role of ASN with respect to the balance between social benefits and risks associated with ionizing radiation.

It was highlighted that transparency and independence are linked in an intimate way. In particular, as ASN communicates about its decisions, it is very unlikely that the Government will take a decision against the ASN position.

In case of a strong disagreement between ASN and the government leading to significant societal issues, both parties will go to the Parliament in order for a decision to be reached.

The independence of ASN is somewhat limited by the budget related issues (no real control of IRSN budget, difficulty in contracting with foreign organization, difficulty in using these funds for hiring people dedicated to a particular project. Limitation in the capability of ASN to contract other TSOs.)

## 2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

### *Recommendations and Suggestions from IRRS 2006 Report*

#### RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- R5 **Recommendation:** ASN has many orders and guides under review and in preparation to further incorporate IAEA standards and WENRA reference levels. This work should be completed as soon as practical as part of the renovation of the French nuclear and radiation safety regulation. This should also create a single, comprehensive set of orders and guidance that are clear and useful to all parties involved.
- R6 **Recommendation:** ASN should initiate and make arrangements to improve the timely reporting of occupational radiation exposure doses for oversight and analysis of radiation protection practices. [Dose information should be made available in a timely manner to individual employees and employers and ASN to help ensure optimization and limitation of radiation exposures].

### *Changes since the IRRS 2006 Mission*

**Recommendation 5:** Since the Mission took place, a set of decrees have been issued by the French Government needed to allow implementation of certain provisions of the Act 2006-686 of June 13<sup>th</sup>, 2006 on transparency and security in the nuclear field (TSN). These decrees are the following ones:

#### **1. Scope and organization of the regulatory procedures:** 5 decrees have been published

- Decree 2007-830 of 11 May 2007 concerning the list of BNIs (decree clarifying the definition of the various BNI categories);
- Decree 2007-1557 of 2 November 2007 concerning basic nuclear installations and nuclear safety regulation of the transport of radioactive materials (decree defining the procedures of the new BNI regime) ;
- Decree 2007-1582 of 7 November 2007 concerning the protection of persons against the hazards of ionizing radiation and modifying the Public Health Code (decree updating the radiation protection procedures defined by the Public Health Code);
- Decree 2007-1570 of 5 November 2007 concerning the protection of workers against ionizing radiation and modifying the Labor Code (decree updating the radiation protection procedures defined by the Labor Code);
- Decree 2007-758 of 10 May 2007 implementing part 1 of Act 2006-686 of 13 June 2006 concerning transparency and security in the nuclear field and modifying the Defense Code (decree updating the regulatory provisions concerning the supervision of defense-related nuclear installations).

#### **2. Operation of bodies and financial issues:** 6 decrees have been published

- Decree 2007-831 of 11 May 2007 determining the procedures for designating and approving nuclear safety inspectors;
- Decree 2007-1572 of 6 November 2007 concerning technical inquiries into accidents or incidents concerning a nuclear activity (decree specifying how these inquiries are to be conducted, particularly the appointment of the investigators);

- Decree 2007-1368 of 19 September 2007 concerning the part-time assignment of certain state civil servants to the Nuclear Safety Authority (decree in particular allowing nomination as ASN regional delegates of the directors of the eleven regional directorates for industry, research and the environment hosting an ASN regional division);
- Decree 2007-1459 of 11 October 2007 creating the Nuclear Safety Authority's joint technical committee ;
- Decree 2008-251 of 12 March 2008 specifying certain rules regarding the composition and working of the local information committees;
- Decree n° 2008-1108 of 29 October 2008 on the composition of the High committee on transparency and information on nuclear security (HCTISN) ;
- *Decree organizing the working of the HCTISN: not yet published. However, ASN has given a positive official opinion on it in November 2008 ;*
- *Decree updating a number of formalities in the BNI tax decree : not yet published.*

Specially relevant is the Decree 2007-1557 of 2 November 2007 concerning basic nuclear installations and nuclear safety regulation of the transport of radioactive materials, that regulates, in particular, the administrative steps to obtain authorization for creating a new BNI, from the application format and content, steps of the authorization, to declare or obtain authorization for modifications of the installations, both in equipment and general operating rules, and describes authorities involved in the process, etc.

Moreover, ASN has already elaborated the draft for a Ministerial order, that when approved by the Government will be mandatory for installations and activities regulated under the TSN Act.

In order to incorporate the IAEA standards and reference levels of WENRA, ASN has initiated a program to elaborate about thirty ASN decisions and other standards to regulate the main processes of utilities and activities. The team received a copy of the schedule to produce all of these standards that goes until 2010, i.e., and perceived a strong commitment to meet this goal. Anyway, emission of ASN decisions are pending of approval of the above mentioned Ministerial order as most of ASN decisions will specify the requirement of the Ministerial order

The team also received a copy of the procedure governing the process of ASN to elaborate decisions and other standards related to BNI, described in a procedure (Ref. ASN/REG/01A) that establishes a very thorough process that takes several steps, from taking into account international standards, consulting the regulated as for their needs, writing down the first draft by a team of experts belonging to ASN and IRSN, review by a dedicated Review Committee (COREL), involvement of the upper management in the revision process prior to ASN Commission approval of the draft document, the way to consider comments of stakeholders, etc., with the overall supervision of an ASN steering committee that monitors the adequate implementation of all the program. The team has considered this recommendation fulfilled and the process of drafting new standards and controlling the overall process is a Good practice.

#### **Findings from the 2009 follow-up IRSS Mission**

##### **Recommendation 5 is closed:**

- The list of standards undertaken through the WENRA and IAEA standards program
- The significant amount of Decrees and standards already issued
- The strong commitment that ASN has demonstrated to meet the schedule of this program

In addition, the team has considered that the process of drafting new standards and controlling the overall process is a **Good practice**.

##### **Recommendation 6 closed.**

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009  
IRRS MISSION**

**BASIS:** **GS-R-1 Section 3.3 (9)** states *“the regulatory body shall ensure that its regulatory principles and criteria are adequate and valid, and shall take into consideration internationally endorsed standards and recommendations;”*

GF1 **Good Practice:** **(from the Recommendation 5):** ASN has created an organization specifically devoted to produce standards that involves ASN and IRSN experts, consults regulated industry, and a system to ensure consistency, completeness and state of the art of the standards produced.

### 3. ORGANIZATION OF THE REGULATORY BODY

#### - *Review and Policy discussion on the Relationship between ASN and IRSN*

#### 3.1. GENERAL ORGANIZATION

##### Considerations and Findings from IRRS 2006

Under the topic “Organization of the regulatory body”, the 2006 mission reviewed general organizational issues, budget, staffing and training, ASN’s advisory bodies and technical support organization IRSN, relationships with the operators and international cooperation. In general, findings were positive and good practices in the areas of training and international cooperation were identified. The review discussed the high turn-over rate of ASN staff and gave respectively one recommendation related to the rotation of positions in ASN.

##### Recommendations and Suggestions from IRRS 2006 Report

###### RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

R7 **Recommendation:** To avoid too fast a turn-over leading to too many people leaving ASN after a short period, ASN should organize and foster more possibilities for rotation of positions within ASN. (*complete, however see new recommendation*)

##### Changes since the IRRS 2006 Mission

The internal organization of ASN has been adapted to the new structure after November 2006.

###### ASN Chart (annex)

ASN demonstrate its willingness to improve its HR policy by a large diversification of its recruitment relying to several fields like: extension of the exchange of personnel between ASN and IRSN, human factors, radiophysics, labour inspection... One of the last signs we find is the recent recruitment of a specialist with a large experience in the field of competency management.

ASN remains deep embedded in the French civil service with a lot of constraints linked with the managements rules. Actions have been taken by ASN to the management of the “Corps des Fonctionnaires Techniques” to extend the duration in the same position within ASN from 3 to 4 years. It remains a slight improvement taking into account the costs and the time dedicated to the training. It is generally considered that an engineer is not very operational during his first year of work within ASN. The ratio between the training time and the operation time remains questionable.

The internal mobility within ASN has been developed this last years but it is always difficult to express a motivated judgement about the effectivity of this solution. The reason is that the internal reorganization of ASN since the change of statute had caused a lot of conjunctural changes and therefore it is premature to assess the actual amount of internal mutation on a more structural base. Therefore the trend on the short period from 2005 to 2008 shows an evident increase but the global impact remains limited (8 to 18 persons on a total averaged amount of about 400).

To consider the style of the management is the third way been investigated starting from the point of view that experts feel better in a cooperative management than in an authoritative one.

As a result the figure related to the seniority of the personal of ASN shows a trend of decrease of the proportion of persons present less than 4 years within ASN. This result is not negligible when we add that the number of posts increase from 378 in 2005 to 432 in 2008.

ASN have also to face a reorganization of the Ministry (MEEDDM = Ministère de l'Écologie, de l'Énergie, du Développement durable et de la Mer).

The 11 regional divisions of ASN are embedded in the framework of the DRIRE (Direction Régionale de l'Industrie et de l'Environnement), large administrative body composed mainly of engineers with similar training where ASN represented about 10% of the personal. The head of division generally fulfils his first employment and is a young civil servant; therefore, the Regional Director (DRIRE) played a not negligible role especially in the relations at high level with the local authorities (Prefets for instance); since 2006 it is was agreed that the DRIRE would dedicate 10% of his work time to ASN.

In the course of 2008 the decision was made to merge some regional directions including DRIRE becoming DREAL; this merge have as consequence that DREAL become larger administrative body with a reduced availability of its director for ASN matters. Moreover the educational background and the professional experience of the Directors shows a very large variety. ASN will be always able to take into account the possible evolutions of the situation.

A first step to cope with this structural change in the administrative environment of the regional seems to increase the initial seniority of the head of division (second employment at least); further steps could be needed.

The combination of the specificities of the French legislative system divided into codes following the domain (Labour, Public Health, Environment, Mines), the specificities of the Administrative management we already pointed out and the specific needs of ASN result in some difficulties in the organization of the inspections.

Fields of activities ASN ↓	Types of inspectors →	Inspector Public Health	Inspector nuclear safety/ INB	Inspector nuclear safety/ Transport	Inspector Radiological protection	Auditor
INB			X	X	X	
Building and operating an establishment of public health		X				
Transport of Radioactive Materials				X	X	
Nuclear installation with a risk of personal irradiation				X	X	
Agreed labs or organisms		X		X	X	X

To establish and to operate the programme of inspections need that the right type(s) of inspectors corresponding to the hereabove table are available.

The division of the French legislation into different codes has also as consequences a strong need for coordination between administration (DG Labour, DG Health, ...). ASN has faced the problem by signing conventions at the national level with the interested partners; the national conventions are completed by regional agreements (at the level of the DRIRE – now DREAL- and Regional division of ASN from one part, and regional direction of the other ministries at the other part.). The conventions have been integrated into the procedures of ASN. We can consider that a high degree of formalization has been reached.

Nevertheless, extra attention is needed to avoid that some problems can occur sometimes in the smaller entities due to the effects of the turn-over combined with the necessity to have various competencies and habilitations. When a judiciary affair occurs, a specific attention is needed to designate the civil servant who have to write the offence statement.

In the first IRRS report we already pointed out the comprehensive programme of training. Training remains one strength of ASN with well defined courses dedicated to the education of the various domain of work defined by ASN: NPP, other BNI (Labs, Factories...) and other nuclear activities (medical, industrial and miscellaneous). At each domain there is a corresponding training with 3 types of qualifications: medical, industrial or miscellaneous. The habilitation is only given after completion of continuously improved courses. The training policy has been developed further with the recruitment of specialized persons become a key topic in the management of human resource.

The new ASN commission which was created in 2006 continues the international its involvement with proactive international work including in taking part of the harmonization actions at the European level: European directive of Nuclear Safety, WENRA, and at international level IAEA Commission on Safety Standards (CSS), Nuclear Safety Convention (CNS), Joint Convention (JC), and MDEP.

The new ASN commission has shown a clear strong motivation in order to avoid to be isolated from any other stakeholders at the Governmental level and has developed a comprehensive programme establishing conventions and protocols with relevant stakeholders at local, national and international level e.g. Protocole entre l'Autorite de surete nucleaire (ASN) et le Service de defense, de securite et d'intelligence economique (SDSIE) and the convention entre l'Autorite de surete nucleaire (ASN) et la Direction de l'action regionale, de la qualite et de la securite industrielle (DARQSI).

The new ASN commission addresses clearly long term views of the regulatory strategy in order to define state policies, principles and criteria to ensure long term safety of people and society as well as advising the Government on long term safety.

The focus of the follow-up review of the organizational issues was on ASN's relationship with its technical support organization IRSN and the follow-up of the recommendation.

Its role as ASN's TSO is thoroughly described in the 2006 report (§3.3 and Annex IV) and therefore is not repeated here. As in 2006, the IRRS follow-up Team appreciates the high scientific strength and merits of IRSN and importance of good cooperation between ASN and IRSN.

During this follow-up mission, ASN and IRSN relationship was dealt with as a follow-up review topic and as a topic of policy discussions. The results are presented below.

### ***Findings of the follow-up Mission***

Since the 2006 mission, ASN has strongly developed administrative aspects of the relationship with IRSN. ASN has established a particular organizational unit (Management and expertise office) which has the coordinating role in the relationship with the IRSN. Accordingly, dialogue and follow-up activities have strongly been increased at all levels between the organizations.

However, in its regulatory function of review and assessment, ASN is very strongly supported by IRSN as was the case also in 2006. This raised some discussions and questions among the IRRS Team members about IRSN's role in review and assessment, which role might appear to be too

strong. It was emphasized that the role of ASN (having sole responsibility of the regulatory function of review and assessment) and IRSN (providing technical support to ASN for this function) should always be very clear. Otherwise there could rise concerns about ASN's technical independence in this regulatory function. To add clarity between the roles, ASN might wish to consider increasing its counterparts' technical capabilities to levels equal to IRSN and requesting in future also better targeted and analytically focused tasks from IRSN.

As is the case with TSO in general and discussed in more detail in the Management System chapter, the Team considered that ASN would benefit from auditing those IRSN's review and assessment functions, which ASN uses, against ASN's MS requirements.

Returning to the 2006 IRRS recommendation 7 (R7: "*To avoid too fast a turn-over leading to too many people leaving ASN after a short period, ASN should organize and foster more possibilities for rotation of positions within ASN*") changes since the 2006 mission are as follows:

ASN is implementing this recommendation. To reduce the turn over, ASN has been developing two approaches:

**ASN has taken actions to implement recommendation 7 with:**

- a clear improvement of the human resources management;
- further development of the training policy, including a sophisticated tool to follow the individual positions; and
- coordination with other administrative bodies.

Furthermore, it appears that the key for a solution is probably not fully in the hand of ASN.

ASN has been developing and implementing internal career advancement arrangements. This has produced some measurable results. However, staff-turn is still, and obviously continues to be, a challenge to ASN in at least two different ways. One hand, it creates pressure to maintain high calibre of staff with the increasing workload ASN is facing. One the other, high staff turn-over creates high costs in terms of recruiting and training expenses as well as time taken from senior staff members from core work into training of new comers.

Therefore, the follow-up conclusion is that ASN is implementing this recommendation, which unfortunately does not seem to be able to solve the original problem of high staff turn-over.

It is necessary to take more proactive actions for exchange experienced staff mainly from ASN including if necessary other organizations to improve their capacity building of ASN considering all regulatory areas where expertise within the regulatory body is necessary.

**Recommendation 7 is closed. Has been incorporated in a new recommendation (see recommendation no. RF1.**

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

- (1) **BASIS:** GS-R-1 3.5 states that "*The regulatory body may also have additional functions. Such functions may include:*
- (1) *independent radiological monitoring in and around nuclear facilities;*
  - (2) *independent testing and quality control measurements;*
  - (3) *initiating, co-ordinating and monitoring safety related research and development work in support of its regulatory functions;*
  - (4) *providing personnel monitoring services and conducting medical examinations;*
  - (5) *monitoring of nuclear non-proliferation; and*
  - (6) *regulatory control of industrial safety.*"

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

- (2) **BASIS:** GS-R-1 3.3 (6) states that *“In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body: shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public;”*
- GF2 **Good Practice:** ASN takes significant part in harmonizing actions at the European level: European directive, and proactive and leading activities at the international level.
- (1) **BASIS:** GS-R-1 3.3 (6) states that states that *“In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body: shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public;”*
- (2) **BASIS:** GS-R-1 3.4 states that *“The regulatory body shall co-operate with other relevant authorities, advise them and provide them with information on safety matters in the following areas, as necessary:*
- (1) environmental protection;*
  - (2) public and occupational health;*
  - (3) emergency planning and preparedness;*
  - (4) radioactive waste management (including determination of national policy);*
  - (5) public liability (including implementation of national regulations and international conventions concerning third party liability);*
  - (6) physical protection and safeguards;*
  - (7) water use and consumption of food;*
  - (8) land use and planning; and*
  - (9) safety in the transport of dangerous goods.”*
- GF3 **Good Practice:** ASN puts strong emphasis to avoid being isolated among relevant stakeholders establishing convention and protocols with local, national and international stakeholders.
- (1) **BASIS:** GS-R-1 3.1 states that *“In order to fulfil its statutory obligations, the regulatory body shall define policies, safety principles and associated criteria as a basis for its regulatory actions.”*
- (2) **BASIS:** GS-R-1 3.2 (11) states that *“In fulfilling its statutory obligations, the regulatory body:*
- GF4 **Good Practice:** ASN commissioners take into account long term consideration and regulatory positions in order to ensure long term safety in France and abroad.
- (1) **BASIS:** GS-R-1 section 4.7 States that *“In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts.”*
- GF5 **Good Practice:** At the side of training we consider that the strong improvement of the training courses with modular composition of the courses and specific modules dedicated to specific area giving a comprehensive education to the personnel could be regarded as a good practice.]
- (1) **BASIS:** GS-R-1 section 4.6 states that *“The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. It is likely that there will be positions of a specialist nature and positions needing more general skills and expertise. The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions.”*
- (2) **BASIS:** GS-R-1 section 4.8 states that *“In undertaking its own review and assessment*

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009  
IRRS MISSION**

*of a safety submission presented by the operator, the regulatory body shall not rely solely on any safety assessment performed for it by consultants or on that conducted by the operator. Accordingly, the regulatory body shall have a full time staff capable of either performing regulatory reviews and assessments, or evaluating any assessments performed for it by consultants.”*

**RF1 Recommendation:** ASN should:

- Improve and facilitate the staff recruitment and the flexibility in order to obtain the necessary experienced staff on time and during the necessary period to carry out the regulatory activities
- Significantly improve the exchange of experienced staff from IRSN and other organizations.

## **POLICY DISCUSSIONS ON ASN-IRSN RELATIONSHIP**

### **Background**

The regulatory functions related to nuclear and radiological safety requires a high level of technical expertise, and this expertise can be shared between a Regulatory body and one or more Technical Support Organization(s) (TSO).

The Regulatory body has to have in-house technical expertise (in particular for review and assessment), and it may be complemented in varying degrees depending on countries by external expert support.

Many organizations are possible:

- A very integrated approach such as U.S. NRC's where the TSO is completely integrated into the Regulatory body (although it also obtains support from national laboratories);
- A separated approach with independent Regulatory and TSO organizations, with varying degrees of separation and size, such as Germany (BMU and GRS), Belgium (AFCN and AVN, superseded by BEL-V) and Finland (STUK and VTT).

The French organization has two main characteristics, per a decision of Government:

- A safety authority and a separate TSO (IRSN);
- The TSO is State-owned, "monopolistic" and with a research mandate.

In this context, the relationship between ASN and IRSN is intended to be based on interdependence and to be complementary. ASN is responsible for organizing and driving the regulatory control, and it takes regulatory decisions supported by technical analyses and assessments conducted by the IRSN.

### **Discussion**

As part of the IRRS Follow-up Mission, there was a policy discussion on the relationship between ASN and IRSN with IRRS team members, ASN Commissioners and ASN Senior Management. The discussion focused on the advantages and risks of the current relationship between ASN and IRSN. The group also discussed possible ways for improving the effectiveness and efficiency of the regulatory oversight of nuclear and radiological safety in France including possible international initiatives.

ASN obtains nearly all its review and assessment support from IRSN and IRSN is involved in nearly every review and assessment organized by ASN. It was noted that, even though ASN obtains strong support from IRSN in the area of review and assessment, in three recent cases ASN has taken a decision contrary to the IRSN recommendation, expressing its independence of judgement and the need to place technical assessments in a wider regulatory context. Through the discussion and other observations during the mission, it was clear the relationship between ASN and IRSN at a working level is very sound and efficient. It was stressed that even though the French system is an extreme case, it has proven itself effective so far.

Since 2006, ASN has taken a number of steps to strengthen the governance of the relationship between ASN and IRSN. This allows ASN to monitor more closely the work of IRSN but IRSN still receives its budget for regulatory review and assessment work directly from the government with little ASN input. In the area of international relations, ASN and IRSN have jointly developed a strategic approach, which provides the government with a coordinated view.

Concerning possible international initiatives, the group discussed the possibility of the establishment of a TSO network, similar to the WENRA initiative for regulators. While this appears to have some merits, the great diversity in size of European TSOs might be problematic. Further, there is a potential for IAEA peer review services to include review of TSO services to regulators as

part of the “review and assessment” review. It was noted that the IAEA is currently developing a Safety Guide that might serve as Terms of References for such a service.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

- (1) **BASIS: GS-R-1 Section 4.4** states that *“The use of consultants shall not relieve the regulatory body of any of its responsibilities. In particular, the regulatory body’s responsibility for making decisions and recommendations shall not be delegated.”*
- (2) **BASIS: GS-R-1 Section 4.5** states that *“The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken.”*
- (3) **BASIS: GS-R-1 Section 4.6** states that *“The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. It is likely that there will be positions of a specialist nature and positions needing more general skills and expertise. The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions.”*
- (4) **BASIS: GS-R-1 Section 4.9** states that *“The government or the regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body; the need or otherwise for such formal advisory bodies is determined by many factors. When the establishment of advisory bodies is considered necessary, on a temporary or permanent basis, such bodies shall give independent advice. The advice given may be technical or non-technical (in advising, for example, on ethical issues in the use of radiation in medicine). Any advice offered shall not relieve the regulatory body of its responsibilities for making decisions and recommendations.”*
- (5) **BASIS: GS-R-1 Section 5.10** states that *“The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout. Additional requirements for the review and assessment of a nuclear power plant are given in the Appendix.”*

RF2 **Recommendation:** ASN should:

- Work with IRSN and the government to allow ASN to have specific oversight of the IRSN budget for regulatory reviews and assessments; and
- Continue to develop its core competence in all areas of review and assessment in order to define and oversee the technical support needed for regulatory purposes.

- (1) **BASIS: GS-R-1 Section 4.4** states that *“The use of consultants shall not relieve the regulatory body of any of its responsibilities. In particular, the regulatory body’s responsibility for making decisions and recommendations shall not be delegated.”*
- (2) **BASIS: GS-R-1 Section 4.5** states that *“The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken.”*

GF6 **Good Practice:** The development of a common strategy for international relations between ASN and IRSN is considered to be a good practice.

SF1 **Suggestions:** Recognizing the above Good Practice, ASN should work with IRSN to extend this approach to develop common strategies in other areas such research, human resources and communication.

## 4. ACTIVITIES OF THE REGULATORY BODY

### 4.1. AUTHORIZATION

#### 4.1.1 NUCLEAR POWER PLANTS

##### Recommendations and Suggestions from IRRS 2006 Report

###### RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- S2 **Suggestion:** ASN should formalize the process already established in letters to the licensee into generally applicable regulations or guides describing the format and content of documents to be submitted by the operator in support of applications for authorization, as well as the principles and criteria to be followed. This suggestion applies in particular to the content of Safety Analysis Reports and General Operating Rules, with due consideration of recently issued IAEA Safety Standards and lessons learned from the WENRA harmonization process.
- S3 **Suggestion:** ASN should consider replacing the existing uniform format of approval letters broadly used for many different authorizations by a system of authorizations differentiated according to the subject and importance of the authorization.
- S4 **Suggestion:** ASN internal procedures describing the process of authorization should be further improved or developed in order to optimize participation of various organizational units in the process, to ensure time limits are set up for processing the authorization, and to fix the rules for recording and archiving justifications for decisions made during the authorization. These internal procedures will also contribute to harmonization of approaches among the sub-directorates.
- S5 **Suggestion:** ASN should continue in collecting experience with internal authorizations and generic authorizations, currently demonstrated as an effective way for enhancing the licensee's prime responsibility for safety, in order to allow for future broadening of their scope without compromising regulatory responsibilities and to take account of the possible impact of competitiveness in the nuclear power industry.
- S6 **Suggestion:** Based on the positive experience gained with the authorization of the EPR reactor in France, ASN should formalize a pre-certification process for possible future generic (site independent) reactor designs in order to provide for high quality and reasonable time of licensing.

##### Findings from the 2009 follow-up IRSS Mission

**Suggestion 2 open:** The Decree 2007-1557 of 2 November 2007 concerning basic nuclear installations and nuclear safety regulation of the transport of radioactive materials, in Articles 4, 8, 9, 10, 11 and 20 and others establishes the set of documents, and their content, to be submitted by the operator in support of applications for any authorization and the timeframe for the submittals and the assessment by ASN, as well as many other details related with the authorization process. The content of the Safety Analysis Report and General Operating Rules are roughly described in the Decree as for their masterlines, however, the details of the format and content is pending to be specified in an ASN decision, scheduled to be produced in early 2010 that is included in the program of standards to meet IAEA standards and WENRA reference level. As the draft of this decision has not been released yet, the team concludes that this suggestion is progressing but pending to be fulfilled.

**Suggestion 3 closed:** ASN should consider replacing the existing uniform format of approval letters broadly used for many different authorizations by a system of authorizations differentiated according to the subject and importance of the authorization.

A three tier system, taking into account the subject and importance, has been established and implemented (TSN and decree 2007-1557, 2.11.2007).

**Suggestion 4 closed:** ASN internal procedures describing the process of authorization should be further improved or developed in order to optimize participation of various organizational units in the process, to ensure time limits are set up for processing the authorization, and to fix the rules for recording and archiving justifications for decisions made during the authorization. These internal procedures will also contribute to harmonization of approaches among the sub-directorates.

ASN is well on its way developing internal procedures for authorization. From identified seven authorization procedures, five are completed and in force and two (licensing process, and how to set license conditions) are in draft form.

Participation of various organizational units, ensuring time limits are set up for processing the authorization, setting requirements with respect to recording and archiving justifications for decisions made during the authorization are taken into account. Based on the interviews, the value of the internal procedures to harmonization of approaches among the sub-directorates is recognized.

**Suggestion 5 closed:** The Decree 2007-1557 regulates licensee modifications, both equipment and GOR modifications (see Recommendation #21). Besides, ASN issued in July 2008 a “Decision for setting up a system for internal authorizations at BNI”, that was endorsed by a Ministerial order of the Ministry of Ecology, Energy and Sustainable Development in September 2008. ASN decision establishes the scope of Internal authorizations, requirements of the licensee system to use Internal authorization, including internal control and requirements of information to be sent to ASN; the system has to be formally approved by ASN for each licensee before being used and can be suspended or cancelled by ASN.

**Suggestion 06 Pre-certification of New Design closed:** The intention of Suggestion 06 is to encourage ASN to develop a legislative framework which enables effective and timely regulatory review for basic safety design even before the formal authorization application review for creation of a new design reactor, e.g. by providing a “pre-certification process”.

According to the Article 6 of the Decree 2007-1557 “any person intending to operate a basic nuclear installation may, prior to initiating the authorization decree procedure related to the creation stage” can “ask ASN for its opinion concerning all or some of the options it has chosen to ensure the safety of this installation”. With this provision, discussion between a future operator and ASN became possible in the legislative framework.

This provision is not exactly same as the “pre-certification process” mentioned by the suggestion by the IRRS team in 2006. Since all the formal authorization application of BNI in France must be done for individual plants, however, the provision is reasonable and completely fulfills the intention of the suggestion.

Suggestion 2 to 6

ASN has pending the implementation of Suggestion 2 because it is pending to be even drafted ASN decision, regulating the content of submittals for BNI (GOR, SAR). Therefore, the suggestion keeps open.

ASN has implemented Suggestion 5 through the Decree 2007-1557 and an ASN decision endorsed by a Ministerial Order, the Internal authorizations have been fully regulated. Therefore, the suggestion has been fulfilled.

ASN has implemented Suggestion 6 through the Decree 2007-1557 that provides an alternative to the precertification process. Therefore, the suggestion has been fulfilled.

#### 4.1.2. RESEARCH REACTORS

##### Considerations and Findings from IRRS 2006

The 2006 IRRS Mission found that the authorization process in France for research reactors is generally the same as for other BNI facilities, with some differences due to differences in levels of risk. ASN guidance existed on how to proceed with authorizations for modifications and revisions of documents and how to classify modifications for research reactors based on the associated safety risk. For technical assessments by the regulator, IRSN expertise was used extensively. In the case of the Phenix fast reactor, it was noted that the expertise resides almost exclusively within IRSN.

ASN had established performance targets related to the timeliness of regulatory decisions and response to a licensee's submission or request. However, IRSN had not adopted these timeliness goals or targets although IRSN provides a crucial service in ASN's ability to meet their performance targets.

The programme for internal authorizations for research reactors was found to be a Good Practice where the licensee could propose an internal authorization for low risk modifications. Generally, in research reactors internal authorizations were used more extensively than in NPPs due to the generally lower level of risk. ASN evaluated the proposal submitted by the licensee, typically with support from IRSN.

The process for authorization for new BNIs was well defined but requirements for preliminary decommissioning plans and financial guarantees were not formalized.

##### Recommendations and Suggestions from IRRS 2006 Report

###### RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- S7 **Suggestion:** The timely completion of IRSN reviews was raised as an area requiring improvement. As an example, ASN has performance targets for response to operators of authorization requests. However, there is no means by which ASN can require complementary performance measures of IRSN. ASN may consider further refining these key interlinkages with respect to review and assessment performance management with IRSN.
- S8 **Suggestion:** ASN may want to consider formalizing their review and approval programmes for financial guarantees and the associated preliminary decommissioning plans in advance of initial authorization for new BNIs.

##### Changes since the IRRS 2006 Mission

Since 2006, ASN decided to establish a consistent approach for the authorization of all BNIs. To this end, a Procedural Decree (2007-1557) was issued in 2007 that clearly defines the authorization process and the requirements for an application for an authorization. This was a major step in the creation of a comprehensive regime for BNIs.

Consistent with French law, the decree defines timelines for ASN to respond to authorization requests. The decree formalizes the approach that ASN was using for research reactors for internal authorizations and allows for complete delegation of low risk modifications to the licensee. ASN is in the process of approving this approach for CEA.

**Suggestion 7 closed:** To further clarify the relations between ASN and IRSN, a MOU covering the activities during the current year is established. There is then a cascade of documents to control the relationship: MOU at the upper level, a protocol giving an inventory of the prioritized actions,

and the way to organize the follow-up of these activities. They have also created “document-cadre” dedicated to specific areas (as an example: common framework for expertise actions, rules and practices for IRSN experts participating to inspections by ASN).

It is also important to stress that entities have designated specific interlocutors dedicated to the cooperation. Within ASN, the “Management and expertise office “ [*Mission expertise et Animation*] is charged with the coordination with IRSN. A similar structure exists in IRSN with a well-identified interlocutor. There are regular coordination meetings between these interlocutors.

ASN has also developed a quality evaluation sheet for expert reviews performed by IRSN. The respect of the deadlines is assessed along the technical quality, the pertinence of the deliverable and the quality of the exchanges. These sheets are collected and monitored by the coordination office mentioned above.

**Suggestion 8 closed:** Concerning requirements for financial guarantees, ASN has taken two steps to implement the suggestion. Firstly, the 2007 Procedural Decree mentioned above includes requirements for decommissioning plans and financial requirements. Secondly, another decree was issued in 2007 (2007-243) that defines requirements for decommissioning financing. ASN has also been updated their guide on decommissioning.

#### ***Findings from the 2009 Follow-up IRRS Mission***

**Suggestion 7 and 8 are closed.**

ASN has implemented Suggestion 7 and this has resulted in a better structured relationship with IRSN including:

- coordinating function have been created at each side;
- the key-linking documents (MOU, protocol) and supporting documents are in place; and
- an evaluation of the action of the IRSN take place within ASN.

ASN has implemented Suggestion 8 through the issuance of the Procedural Decree and the decree 2007-243.

**No Recommendations, Suggestions or Good Practices from the Follow-up Mission.**

#### ***4.1.3. FUEL CYCLE FACILITIES***

##### **Considerations and Findings from IRRS 2006**

The system of authorizations is the same for all BNI. Therefore the authorization process for Fuel Cycle Facilities was found to be to a large extent the same as for other BNIs, and including a creation decree with associated safety documents, authorization of effluents, and authorization of modifications.

##### **Recommendations and Suggestions from IRRS 2006 Report**

**No recommendations were identified during the 2006 mission in this area**

##### **Changes since the IRRS 2006 Mission**

Since 2006, as mentioned in the section above, ASN decided to establish a consistent approach for the authorization of all BNIs. The Procedural Decree (2007-1557) now defines the authorization process and the requirements for an application for an authorization for Fuel Cycle Facilities. This consistent approach will allow the approach used for internal modifications in research reactors to be applied to Fuel Cycle Facilities. ASN has started discussions with Avera, their major licensee in this area, about this approach to minor modifications.

#### ***Findings from the 2009 Follow-up IRRS Mission***

## No Recommendations, Suggestions or Good Practices from the Follow-up Mission.

### 4.1.4. MEDICAL PRACTICES

#### Considerations and Findings from IRRS 2006

In 2006, facilities wishing to use radiation for medical purposes were required to submit an application for authorization to use CT scanners for diagnosis; radionuclides in nuclear medicine; and external beam radiotherapy installations; or to submit a notification (declaration) for medical and dental radiographic installations. The use of digital angiography had recently been changed from requiring an authorization to requiring a notification, bringing these installations in line with conventional angiography. The documentation and controls needed for a dental x-ray practice were the same as those required for a medical x-ray facility.

ASN had issued internal guides for processing applications for all uses requiring an application except nuclear medicine, which was in advanced draft form. ASN had developed clear requirements for what needed to be submitted in applications and developed application and declaration forms that provided clear guidance on the format and content of documents to be submitted in support of applications for authorization or in declarations (as acknowledged in Good Practices G9 and G10). However, the IRRS team noted that: (1) some information requested to be submitted in applications may not have added any value to the regulation of radiation safety; (2) some information requested to be submitted for amendments and renewals may not have been relevant; and (3) automatic reminders were not sent to licensees prior to renewal.

Authorization for manufacture and distribution of sealed and unsealed sources was provided by AFSSAPS, as was the assessment of safety of medical devices, including x-ray generators. The IRRS team was informed that AFSSAPS' role in authorizing the manufacture and distribution of unsealed sources was to be transferred to ASN following the implementation of the TSN 2006 Act. Implementation of the TSN 2006 Act would also provide the opportunity for ASN to issue technical decisions to set radiation safety standards for radiology, nuclear medicine, brachytherapy, and external beam radiotherapy installations.

The IRRS team was informed that, at that time, prior authorization from the ARH (the regional health authority) was required to allow the provision of services including radiotherapy and 'sophisticated' diagnostic equipment such as CT scanners, and that INCa, the French national cancer institute, would assume a new role in the definition of approval criteria for authorizing certain medical activities. At that time, the regulatory mechanisms for INCa had not been completed and the relationship between the INCa authorization criteria for an activity and ASN authorization for use had not been clarified.

#### Recommendations and Suggestions from IRRS 2006 Report

##### RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- S9 **Suggestion:** ASN should reconsider the categorization of facilities using X-rays in interventional procedures.
- S10 **Suggestion:** Notwithstanding the Good Practice G9, it is suggested that ASN completes the development of its internal procedures (nuclear medicine) to cover all medical practices, considering its own experience feedback.
- R8 **Recommendation:** Considering the decision to change the role of AFSSAPS in authorizing the manufacture and distribution of sealed and unsealed sources, and X-ray generators (with likely transfer to ASN in 2007), ASN will need to develop technological surveys, in collaboration with IRSN, to assess the safety of new medical devices, using current international standards for radiation safety.
- R9 **Recommendation:** The relationship between ASN authorization for use and the future

## RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- INCa authorization for a health practice (e.g. cancerology) must be clarified and formalized.
- S11 **Suggestion:** ASN, through its new powers, should issue technical decisions that set radiation safety standards for radiology, nuclear medicine, brachytherapy and external beam radiotherapy installations.
- S12 **Suggestion:** ASN might wish to review whether the documentation and controls needed for the declaration of a dental X-ray practice should be the same as for the authorization for a medical practice.
- S13 **Suggestion:** Notwithstanding Good Practice G10, it is suggested that, for the purpose of simplifying the process for users, ASN reconsiders some of the information it currently requests.
- S14 **Suggestion:** It is suggested that ASN reviews the information it currently requests for amendment or renewal of an authorization or amendment to a declaration.
- S15 **Suggestion:** ASN should consider sending a reminder letter to licensees prior to the 6 months before the expiry date of the authorization.

### Changes since the IRRS 2006 Mission

**Suggestion 9 closed on the basis of progress and confidence:** ASN has discussed recategorizing the use of x-rays in interventional procedures to require authorization rather than declaration. With guidance from medical advisors, ASN is preparing a regulatory decision to be issued in mid-2009. Considerations in this decision are the risk level of intervention radiology procedures, and whether authorization would provide a higher level of safety than declaration.

**Suggestion 10 closed:** Internal procedures for processing nuclear medicine applications were published in document DGSNR/SD7/DCT/n°29/00.

**Suggestion 12, S13, S14 and S15 closed on the basis of progress and confidence:** ASN informed the IRRS team that a consultation with the medical advisory group and dentists is in progress to review the requirements for dental x-ray practices. The declaration and authorization processes are being simplified for all applicants, reducing the amount of information that is not relevant to radiation safety. ASN informed the IRRS team that the Paris Division is now sending letters to remind licensees that submission of a renewal application is required at least six months before the expiration date and that this practice will be extended to other Divisions in the future.

**Recommendation 8 closed on the basis of progress and confidence:** In a November 2007 decree, the Public Health Code was modified to transfer from AFSSAPS to ASN the authorization of manufacturing and distribution of sealed and unsealed sources. In August 2008, decision 2008-DC-0109 initiated ASN's authorization for distribution and import/export of sealed and unsealed sources. Decision 2009-DC-0108 initiated ASN's authorization of positron emission nuclides produced in cyclotrons. While AFSSAPS continues to have responsibility for the assessment of safety of medical devices including x-ray generators, ASN has participated with IRSN in safety assessments of new devices including portable dental x-ray units, dental cone beam tomography units. ASN informed the IRRS team that a memorandum of understanding with AFSSAPS is being drafted regarding radiation safety assessment of devices.

**Suggestion 11 closed on the basis of progress and confidence:** ASN informed the IRRS team of existing and draft technical decisions applicable to radiology, nuclear medicine, brachytherapy, and external beam radiotherapy installations. The IRRS team was provided a copy of the draft NFC 15-160 series for medical and dental x-ray units and two radiation oncology guides.

**Recommendation 9 closed on the basis of progress and confidence:** In March 2007, the Public Health Code was modified to allow the health authority to authorize oncology practices, including

radiotherapy. In November 2007, the Public Health Code was modified to require a single authorization, by ASN, for use of a linear accelerator. In June 2008, criteria for radiotherapy practice established by INCa, were issued according to the Public Health Code. ASN provided a draft copy of a convention between ASN and INCa to define the roles of each agency.

#### **Finding of the 2009 follow-up IRRS mission**

**Recommendations 8, 9 and Suggestions 9, 11, 12, 13, 14, and 15 are closed on the basis of progress and confidence.**

**Suggestion 10 is closed.**

Changes which were forecast to take place in 2006 have very largely been implemented, although continuing action is being taken on some items.

#### ***4.1.5. INDUSTRIAL AND RESEARCH PRACTICES***

##### **Recommendations and Suggestions from IRRS 2006 Report**

###### **RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION**

R10 **Recommendation:** ASN should adapt its existing guidance to form formal procedures in the framework of its management system, covering the use of radiation sources in all practices connected with industry and research authorized by SD1.

##### **Changes since the IRRS 2006 Mission**

**Recommendation 10 closed:** At the time of the 2006 IRRS mission, ASN had a procedure in place (Note ASN/AUT/01) that applied generally to the process of issuing licenses. In response to Recommendation No. 10, the scope of this procedure was expanded in May 2008 to include radiation source applications associated with industrial and research uses. Also, Procedure ASN/AUT/21 was issued in September 2008. This procedure formalized ASN's administration of the licensing process for radioactive sources that are used in the industrial, research and medical applications. Included in this procedure are flowcharts that address the handling of license applications, time schedules for the handling of certain steps in the authorization process, assignment of signature authority for licenses, and references to technical guidance documents that should be applied to the review of specific practices such as radiography (Guide SD1 n° 1-SD-FS 24) or radiotherapy (Guide d'instruction DGSNR/SD9/DCT/ N° 9/00). Technical guidance documents of this type were discussed in Section 4.1.5 of the 2006 IRRS Report. Since the 2006 IRRS mission, a draft technical guidance document that addresses the review of authorization requests for small sealed sources has been developed (Projet de Guide interne/AUD/DIT/01).

A working group comprised of representatives from ASN/DIS and ASN/DIT has developed a proposal that would make more efficient, and harmonize the processing of authorization requests by these two directorates. Features of the proposal included the simplification of application forms, decreases in the number of required documentation to be submitted and harmonization of the requirements for applications between different sectors, i.e., the medical and industrial sectors. A report detailing this proposal was presented to the Commissioners; however, final action on its implementation has been delayed pending consultations with suppliers, users and other governmental bodies.

##### ***Findings of the IRRS Follow up France mission 2009***

**Recommendation 10 is closed.**

#### ***4.1.6. WASTE FACILITIES***

##### **Considerations and Findings from IRRS 2006**

The 2006 Mission assessed the authorization of waste facilities in France according to four main areas: predisposal management and storage of radioactive waste; discharge control; decommissioning; and, disposal. The waste facilities would normally qualify as BNIs in the terminology of the TSN law and the general process of authorization will thus be similar. It was observed that the operator is responsible for developing a waste plan, which incorporates a number of elements ranging from the minimization of volumes and toxicity of waste to long-term management solutions.

Discharge control for nuclear, industrial and medical facilities is carried out in principle according to the legislation on public health. ASN is authorized to implement the provisions of the legislation in the nuclear and medical field, whereas some industrial applications and uses of radiation are outside ASN mandate. Such facilities are referred to as ICPE facilities (installations classified for the protection of the environment).

As to decommissioning and disposal, procedures for authorizations were found to be established, under way or planned (as in the case of geological disposal where research work is ongoing). A good practice in the decommissioning area was identified, related to the review of the technical modifications being part of a decommissioning project.

#### **Recommendations and Suggestions from IRRS 2006 Report**

*There were no recommendations or suggestions made during the 2006 IRRS mission in this area.*

#### **Changes since the IRRS 2006 Mission**

Many industrial installations in France are regulated as ICPEs. They are licensed by the Prefect after an investigation by local offices of the Ministry of the Environment. The nature of the collaboration between ASN and the Ministry was the subject of some discussion during the follow-up mission. At the national level, the Ministry of the Environment is in charge of the relations between ASN and the government, and is also in charge of the ICPEs using radioactive materials. This secures harmonisation in the regulation of BNIs and ICPEs. The collaboration is also strong on the regional level, governed by agreements between the parties, which secure efficient regulation as well as maintenance of a comparable level of control across all activities (nuclear, medical, research, educational, industrial) involving radiation.

Other observations made during the 2006 mission remain valid. While there were no recommendations and suggestion regarding authorisation, there were, however, some recommendations and suggestions regarding review and assessment, regulations and guides, as well as with regard to the infrastructure for waste management.

#### *Findings from the 2009 Follow-up IRRS Mission*

No recommendations, Suggestions or Good Practises from the Follow-up Mission

## **4.2 REVIEW AND ASSESSMENT**

### **4.2.1 REVIEW AND ASSESSMENT OF NUCLEAR POWER PLANTS (NPPS)**

#### **Recommendations and Suggestions from IRRS 2006 Report**

#### **RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION**

- R11 **Recommendation:** ASN shall demonstrate that they have the necessary qualifications and expertise to be accepted as a Notified Body for N1 Class equipment as required by EU directive 97/23/CE and to comply with international standards.

## RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- S16 **Suggestion:** In light of improving effectiveness and efficiency in the safety review process, ASN:
- should make more comprehensive use of the graded approach, in particular for general operating rules;
  - should ensure that external technical support is available and utilized as necessary to support the variance in the regulatory body activities, including identification of acceptable consultants;
  - should establish an internal guideline for review and assessment of PSR.
- S17 **Suggestion:** ASN should consider establishing guidance that ensures that those subjects of NS-G-2.10 that will be reviewed outside of PSR are accomplished with the same thoroughness and with at least the same frequency as in other formal review processes. The reason for exclusion from PSR should be well justified. ASN should reevaluate the extended implementation of modifications following a PSR, taking into account an acceptable ranking method for implementing modifications. The results of this then should be incorporated in the guideline.
- S18 **Suggestion:** ASN should review and compare the ageing management assessment methods used by each SD in order to ensure consistency.
- S19 **Suggestion:** ASN should require licensees to do an integrated assessment of all events and report this to ASN periodically. ASN should increase the sources of evaluated foreign events.

### *Changes since the IRRS 2006 Mission*

**Recommendation 11 is open: Qualifications and Expertise on N1 Class Equipment:** In France, the conformity of the heavy equipments used in BNIs is strictly assessed. Especially, N1 class equipments, which are used as pressure boundary to contain radioactivity, are inspected directly by the Nuclear Pressure Boundary Equipment Department (DEP) of ASN, while other heavy components are inspected by notified bodies certified by the Administration. The inspection is carried out throughout their service life, including design, manufacturing and in-service stages.

Since high competence is required for such inspections, EU directive 97/23/CE requests EU authorities to fully comply with the 17020 ISO Standard. While the notified organizations already satisfied the ISO Standard, ASN/DEP, which is responsible for inspection of the most important equipments, has not been formally certified yet. However, the DEP has started to develop a higher level of management system for achieving its mission and one of those efforts is to satisfy the ISO Standard by 2011.

**Suggestion16 is open: Effective and Efficient Safety Review Process:** ASN is responsible for establishing effective and efficient regulation and developing necessary regulations.

#### Part1: Graded Approach for GOR

For the IRRS suggestion that “ASN should make more comprehensive use of the graded approach, in particular for general operating rules (GOR)”, ASN is preparing a regulatory decision to formalize the content of the GOR. Right now it is under writing stage by a working group. The GOR is to include all the utility’s activities, including technical specifications, periodic tests, radiation monitoring, maintenance, safety management, etc.

The top level documents which the operator must follow are the Safety Analysis Report (SAR) and the Impact Assessment Report (IAR) (Articles 8, 9 and 10 of the Decree 2007-1557). The Decree establishes that the scope and depth of such reports shall be commensurate with the size and the hazards of the installation. The GOR is to be developed as a single document for the operator based

on the concept of graded approach. The intention of the GOR is to specify to the operators how to fulfil the requirements from the SAR and IAR

It should be noted that the “Safety” in the Decree is not same as the radiological safety defined by the IAEA Standards. The “Safety” in the Decree (and hence in SAR, IAR and GOR) not only includes radiological safety of public and workers but also includes industrial safety and protection of the environment.

ASN includes in its regulatory project a Decision to specify the content of GOR. The team concludes this suggestion has been taken into account in the Decree 2007-1557 and needs further development throughout an ASN decision that is scheduled to be issued.

## Part 2: PSR Review Guideline

ASN has not initiated yet any procedure for providing internal guidance as to how to assess the PSRs. Neither has any plan to produce it in the next future, so that the Suggestion, in this regard, should be kept.

**Suggestion 17 is closed:** This suggestion is mainly referred to two issues:

- i) lack of a guidelines for the content of the PSR,
- ii) need for ranking the modifications result of the PSR according to their safety significance, and prioritize their implementation consequently.

A guideline for the content of the PSR is in progress and the team considers it is well addressed. See more details in Suggestion 35 about a very similar topic, that the team considers has been completed.

The classification of design modifications according to its safety relevance has been already defined at the level of the Decree 2007-1557 and an ASN decision is scheduled to be issued specifying the details of how to manage the modifications according to their safety relevance. There is a Recommendation about regulation of modifications (Recommendation 24) that deals deeper with this very subject and the team has concluded it has been completed.

**Suggestion 18 is closed Ageing Management:** Ageing management is important for many of the French NPPs and ASN set up a working group to summarize the ageing-related issues (Letter from DG to Commissioners on 2 July 2008). In particular, ASN required EdF to analyze the effects of ageing in the third PSR process of 900 and 1300 MWe PWRs (i.e. when the plant is operated more than 30 years).

Responding to ASN request, EdF developed a generic ageing management method with a matrix to cover all the materials in the safety related SSCs (structures, systems and components) and all the ageing phenomena of those materials and submitted it to ASN in 2004. ASN reviewed the method with support of IRSN and agreed with the method with some conditions, through a letter signed off in late 2006. For example, the method is for generic ageing management and, when it is applied to an individual plant, it is required to take into account characteristics specific to that facility and its site conditions.

This ageing management method is now implemented in PSR and the operator must submit a paper of ageing analysis results for each material by one year before the outage.

**Suggestion 19 first part is closed, second part is open:** The suggestion, in fact, contains two parts:

- ASN should require licensees to do an integrated assessment of all events and report this to ASN periodically.
- ASN should increase the sources of evaluated foreign events

ASN should require licensees to do an integrated assessment of all events and report this to ASN periodically.

The team has been informed of the annual report sent by each plant to ASN covering an overall analysis of the operation along the year regarding nuclear safety and radiological protection, named “Analysis of safety and radiological protection at the plant of (name) during the year (year)”. Although this report contains a short section devoted to the analysis of their internal events, the team considers it does not meet the purpose of this suggestion that claims for an integrated examination. Besides, the Inspector General of EdF prepares another annual report named “Report of the General Inspector for the Nuclear Safety and Radiation Protection”, that is published for informing the public, that does not include any integrated analysis of operational events, just picks on some significant ones and describes the work in progress about them.

The team was aware of the requirements on reporting and analysis of events at each plant: reporting criteria, content, timing for submission to ASN, etc. However, presently there are no provisions for such as an integrated report as the one suggested in the IRRS Mission. Consequently, the team considers that this part of the suggestion should **remain open**.

ASN should increase the sources of evaluated foreign events

ASN has approved in January 2009 the Note ASN/INC/01 “Application of Experience Feedback” that spells out its internal process to analyse the operational experience (OE). The events that input the process are all events occurred at French BNI, databases on events of the US NRC and IAEA, events reported by regulators of other countries, the media and any event known through other sources of open information, such as telephone calls.

The Note is not very specific about the events reported by other countries, but the team considers that if other countries do not communicate an event, e.g., through IAEA Incident Reporting System (IRS), or bilateral exchange of information, ASN has little chances to get appropriate information that allows assessment of the relevance of events to their BNI. In the other hand, the team considers little rational a search of events through the webpages of the regulator of each country, having in mind the differences in approaches, scope and variable quality of information provided in such webpages, plus a waste of resources that may be better used in other purposes. The team considers that the international agencies, such as IAEA, have the right to claim to member countries to provide reports of any domestic event potentially relevant in other countries, throughout the existing systems, such as the IRS.

In conclusion, the team considers that ASN, according to the Note ASN/INC/01, is already covering the suggestion and any further improvement of the exchange of operational experience among different countries, that may be relevant to French BNI, relies in the IAEA that can strengthen the existing system if it concludes they are not working properly.

In conclusion, the team considers that the Note ASN/INC/01 describes an appropriate set of inputs of operational experience to analyze and this part of the suggestion has been satisfied.

Findings from the 2009 follow-up IRSS Mission

ASN has pending the implementation of Recommendation 11 because the Nuclear Pressure Boundary Equipment Department (DEP) of ASN has not been formally certified as a Notified organization yet, however it has plans to get the certification by 2011.

**The suggestion 16** has three parts. Regarding part 1, graded approach for GOR, the team has found that this suggestion has been taken into account in the Decree 2007-1557 and needs further development throughout an ASN decision to specify the content of GOR that is included in ASN regulatory project. So that the team concludes that, although it is in progress, is still **open**.

The second part of Suggestion 16, deals with the need for ASN to establish an internal guideline for reviewing PSR. ASN has not initiated yet any procedure neither has any plan to produce such a guide it in the next future, so that the Suggestion, in this regard is still **open**.

**Suggestion 17**, related to different aspects of PSR, content of submittals and management of modifications, the team considers that having into account the Decree 2007-1557 and other ongoing activities, the suggestion has been well addressed and may be **closed**.

**Suggestion 18** deals with ageing management. As ASN has already reviewed and accepted a method proposed by EdF, the team considers the suggestion **fulfilled**.

**Suggestion 19** deals with operational experience in two parts: i) ASN should require licensees to do an integrated assessment of all internal events and external experiences selected according to criteria established by ASN, and report this to ASN periodically; ii) ASN should increase the sources of evaluated foreign events. The team considers that the first part is still open, while the second part may be considered **closed part one is open**.

#### 4.2.2 REVIEW AND ASSESSMENT OF RESEARCH REACTORS (RR) AND FUEL CYCLE FACILITIES (FCF)

##### **Considerations and Findings from IRRS 2006**

The following items were evaluated and compared with the activities for NPPs in 2006: PSR (including ageing management), experiments, general operating rules, modifications, PSA application, operating experience feedback and internal authorizations.

One observation was that no overall PSA application for the determination of risk for the various facilities was used due to the large variation in individual designs. However, there were some dedicated and specific applications that are utilized in both types of facilities areas.

##### **Recommendations and Suggestions from IRRS 2006 Report**

*There were no recommendations or suggestions made during the 2006 IRRS mission in this area*

##### **Changes since the IRRS 2006 Mission**

The policy decision by ASN to have a common high-level approach for BNI has resulted in the clarification of the review elements for non-NPP BNI. The 2007 Procedural Decree (2007-1557) establishes a standard list of requirements for BNIs associated with authorization. With this decree, the basic elements requiring review and assessment by the regulatory body are defined including requirements for PSRs. ASN is also working on an Ministerial Regulation that will further define the technical requirements for BNIs. This will include requirements for some level of probabilistic analysis for all BNIs. This approach is further discussed in Section 4.4.1.

##### **Findings from the 2009 IRRS Follow-up Mission**

**No Recommendations, Suggestions or Good Practices from the Follow-up Mission.**

#### 4.2.3 MEDICAL PRACTICES

##### **Considerations and Findings from IRRS 2006**

The professional societies in radiology, dentistry, nuclear medicine, and radiation oncology were developing, in conjunction with other bodies including ASN, publications that include guidance on indications for appropriate examinations or procedures. Adherence to these as they became available, should be the basis for the implementation of justification.

Discussions during the IRRS mission suggest the regulation in France of the use of radiation in biomedical research needed further development. To this end it was suggested that the role of ASN

is to require that all research proposals submitted contain a statement that radiation is, or is not, being used, and that guidance and approval be channeled through an ethics committee.

Medico-legal uses of radiation were being reviewed, particularly in the context of occupational medicine.

A recent accident had demonstrated the need for a greater awareness in medical radiation facilities of the need to report any accident to ASN as soon as they became evident.

### **Recommendations and Suggestions from IRRS 2006 Report**

#### RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- R12 **Recommendation:** ASN should consider lobbying government and the appropriate ministries with a view to further resources being made available to increase the number of medical physicists.
- S20 **Suggestion:** That ASN encourages and assists the professional societies so that publications are available on justification for all uses of radiation in medicine. ASN should explore means for ensuring adherence to the guides.
- R13 **Recommendation:** That ASN sets up a system to ensure appropriate justification of persons exposed to radiation as a result of being in biomedical research trials, where the use of radiation is not the focus of the research.
- R14 **Recommendation:** That ASN ensures that the review of medico-legal uses of radiation takes into account the current international recommendations of the IAEA, WHO
- R15 **Recommendation:** That ASN performs a review of all the orders and circulars and the UTE standards to ensure that the technical requirements for ensuring optimization of medical exposures in external beam radiotherapy, brachytherapy, nuclear medicine, interventional radiology, medical radiology and dental radiology meet current international standards, including the IAEA BSS and other documents.
- S21 **Suggestion:** That ASN considers means for extending to existing X-ray machines (especially those used primarily for children) the commendable regulatory requirement for new X-ray machines to be fitted with dose measuring devices.
- S22 **Suggestion:** ASN should assist IRSN in exploring all means to help users comply with the requirement for reporting doses. ASN needs to establish with IRSN how the collected information is to be fed back into the regulatory programme.
- S23 **Suggestion:** That ASN works with the appropriate bodies to ensure that harmonized guidance for patients undergoing diagnostic and therapeutic procedures using radionuclides are issued as soon as possible.
- S24 **Suggestion:** That ASN should considers carefully, taking into account the type of medical exposure, what information is required to be kept so as to avoid an unnecessary administrative burden on the medical practitioner.
- S25 **Suggestion:** ASN investigates all means of making licensees more aware of the need to immediately report any accidental medical exposures, and why such immediate reporting will help radiation protection.

### **Changes since the IRRS 2006 Mission**

Adverse events in radiotherapy have given particular focus to regulatory oversight of this practice. External beam therapy is provided to nearly 200,000 patients each year in France, with treatments carried out in 180 centres equipped with about 400 radiotherapy machines (primarily linear accelerators).

In June 2007 ASN introduced a system for declaring significant events relating to patient protection, and an event severity scale has been developed jointly with the French society for radiotherapeutic

oncology to aid communication on the significance of reported events. Since 2006 several events have been investigated.

An international conference on radiation protection of patients in radiotherapy is being organized by ASN to take place in Paris 2-4 December 2009.

As a response to the concerns about events in radiotherapy centres, the requirements for quality assurance in centres and the examination of these in ASN inspections have been highly detailed to the extent that they now go somewhat beyond issues related to patient protection and accurate dose delivery. Voluntary guides (ASN Guide 4: Guide d'auto-évaluation des risques encourus par les patients en radiothérapie externe, and ASN Guide 5: Referentiel de mangement de la securite et de la qualite des soins de radiotherapie, guide d'application pour la mise en oeuvre des obligations d'assurance de la qualite en radiotherapie) have been developed in conjunction with other organizations. Guide 4 was developed by ASN in association with SFRO (radiation oncologists) and SFPM (medical physicists), while Guide 5, which is based on ISO 9001, was developed in association with organizations such INCa, SFRO and SFPM. The Guides are broader in scope than accurate dose delivery, quality controls, and radiation protection of patients, but their requirements have been incorporated in ASN inspection guidance.

Requirements for in-vivo verification dosimetry have been introduced. Further a Decision of 27 July 2007 requires newly commissioned equipment or a change in photon energy to have external verification arranged by AFSSAPS before first clinical use.

**Recommendation 12 is closed:** ASN in 2007 carried out an assessment of the need for additional medical physicists. Sixty out of 167 centres (40%) were unable to comply with the requirement for a physicist presence during radiotherapy. In 2008 42 new physicists graduated with diplomas adding to the 320 medical physicists in France in 2007. The diploma qualifies graduates for work in radiotherapy, x-ray diagnosis and nuclear medicine, but most are employed in radiotherapy. Diploma course entrants have required a masters degree with radition physics as a key component, but consideration is being given to modifying the entrance requirements. Five universities currently offer the masters course, but intake numbers have been limited to 80 per year. The completion of the diploma in medical physics requires a further 14 months study, 2 months devoted to theoretical work and 12 months in training hospitals. The present training hospitals are able to offer places to only 55 students. The results of the review have been transmitted to the Health Ministry and a press release issued on 15 April 2008. The Health Ministry has stated that the numbers of physicists must double, and has committed funding to support this. A modification to the Ministerial Order of 19 November 2004 was issued on March 18<sup>th</sup> 2009 to alter the entrance requirements for the diploma course. However not only more university places but more hospital training positions are required. It is doubtful that new diploma graduates would have sufficient on-the-job experience to demonstrate a sufficient level of competence to be able to function unsupervised.

ASN has carried out its responsibility to bring the physicist shortage to the attention of the Health Ministry. It is unlikely that the shortfall in numbers will be met for at least 5 years, and this implies some extension of transitional arrangements for licensing of non-complying centres will be required for their continued functioning.

**Suggestion 20 is closed:** In 2005, ASN supported the publication of a guide about the justification of radiological examinations, for use by radiologists, nuclear physicians, and GPs. Guidance on x-ray technique selection has also been prepared. More convenient ways to use the GP guide are being studied. Following a meeting on 6 January 2009 between ASN and the French Radiology Society, it has been agreed that the imaging referral guidance should be promoted through decision support software used by GPs and targeted advertisement in the medical press (Note d'information Audition du Conseil professionnel de la radiologie française par le collège de l'ASN, 23 February 2009).

**Recommendation 13 is closed on the basis of progress and confidence:** ASN notes the competent body for justification of biomedical research according to BSS § II,8 (b) is an ethical

committee. However, such committees need appropriate radiation dose and effects information to allow an informed decision of the risk of proposed procedures. ASN has asked the Ministry of health to appoint radiation protection experts to the ethical committees. ASN also plans to meet the president of the national committee (“committee for patient protection”) in 2009 on this matter.

**Recommendation 14 is closed::** The Sports Code has been amended (Ministerial Order of 28 February 2008) so that the provisions of the Public Health Code apply to sportspersons, i.e. the same principles of justification and optimization of exposure are to be taken into account. Prisoners may be x-rayed for TB detection, but the extent of the practice is not known.

**Recommendation 15 is closed on the basis of progress and confidence:** ASN is currently drafting several technical decisions on requirements applicable to radiology, nuclear medicine, brachytherapy and external beam radiotherapy installations. A technical decision on quality assurance for brachytherapy and external beam radiotherapy has been issued in July 2008 and approved by the Government in March 2009. These decisions will replace the existing one. They enforce optimization of the medical exposure.

ASN has issued a guide on self-assessment of risks in external beam radiotherapy, which in 3 chapters develops a risk scoring system dealing with risks that may occur in the treatment of the patient, equipment related risks, and organisational errors. Risk analysis is to be made mandatory by 2011.

ASN is also member of a working group, led by UTE, on a review of UTE standards for medical and dental x-ray devices.

**Suggestion 21 and S22 are closed::** ASN is currently updating the diagnostic reference levels (NRD) as a means of optimizing doses in diagnostic radiology and nuclear medicine. The process of data submission to IRSN is being simplified to encourage widened hospital participation in input to the data base, and an ASN circular in July 2008 requested users to report doses. The results for the period 2004-2006 will be used to revise the current reference levels.

ASN has also submitted a proposal to the Health Ministry in July 2008 for requirements for new x-ray equipment to be fitted with dose measuring devices. Following a meeting of 6 January 2009 between ASN and the Professional Council of French radiology (G4), it has been agreed that ASN should focus its action on x-ray equipment manufactured after 2004. G4 considers that paediatric exposure is not a major radiation protection issue in conventional radiology. Interventional procedures are performed in a few centres where dose measurements systems are available. However G4 calls for ASN action to encourage CT scanner manufacturers to incorporate dose measurements systems that give results for children (in addition to CTDI values for adults).

**Suggestion 23 is closed::** Harmonized guidance for patients undergoing diagnostic and therapeutic procedures using radioiodine have been issued by ASN in January 07. Recommendations of the Public Health Council are also available on their internet website.

**Suggestion 24 (and S02) is closed::** ASN has reviewed the information required from and maintained by different categories of medical practitioner licence holder. A report has been published that formalizes the content of the documents to be submitted during the authorization process, and also simplifies the paperwork for applicants. The resulting process is also more consistent, whether the authorization is required for medical or industrial use. This report is to be enforced by a regulatory decision of ASN "content of authorization folders" in mid-2009, and comprehensive guides will follow.

Similar guidance for source suppliers authorisations was published in July 2008.

To further simplify the administrative procedures, ASN is considering setting up web based declaration forms. ASN is also modifying the event reporting criteria for less significant events. In

2008 the number of notifications in radiotherapy was 208 from 56 hospitals (31% of the total radiotherapy centres).

**Suggestion 25 (and Recommendation 06) is closed:** ASN has published event reporting criteria and a communication strategy for medical events. A classification scale for events has been introduced in July 07 and updated in July 08 (“ASN-SFRO scale for dealing with radiation protection events affecting patients undergoing a radiotherapy procedure”). Reports on investigated events are published on the web site according to the above-mentioned communication strategy.

**Finding of the 2009 follow-up IRRS mission**

**Recommendation 14 and Suggestions 20, 21, 22, 23, 24, and 25 are closed.**

**Recommendations 13 and 15 are closed on the basis of progress and confidence**

ASN has carried out its responsibility to bring the physicist shortage to the attention of the Health Ministry, procedure for authorising biomedical research involving human exposure is being formalised, the use of x-rays for medico-legal purposes has been investigated and the Sports Code amended, and technical decisions on use of radiation in medical practices are being further developed. The guide for self-assessment of risks to patients, developed for radiotherapy practice, is a useful initiative, and has the potential to be a tool to alert practitioners to areas of concern in their programmes. The classification scale for events jointly developed with SFRO also has the potential to be a useful tool.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION**

- (1) **BASIS: BSS II.1 (d) states that** “*The practices to which the Standards shall apply include:.....  
(d) any other practice specified by the Regulatory Authority.*”
- SF2 **Suggestion:** In view of the critical role medical physicists have in ensuring accurate dose delivery in radiotherapy, newly graduated physicists should work in liaison with an experienced physicist.
- GF7 **Good practice:** The development of ASN-SFRO severity scale as a tool to convey understanding of the significance of reported events and the development of the risk self-assessment guide for radiotherapy.

**4.2.4 INDUSTRIAL AND RESEARCH PRACTICES**

**Recommendations and Suggestions from IRRS 2006 Report**

*There were no recommendations or suggestions made during the 2006 IRRS mission in this area*

**4.2.5 WASTE FACILITIES, DECOMMISSIONING AND REMEDIATION**

**Considerations and Findings from IRRS 2006**

The 2006 Mission noted that the safety of waste facilities, as other BNIs, were periodically reviewed. This had not been mandatory in the past and did not extend to ICPEs, e.g. the repository for very low level waste at Morvilliers and operated by ANDRA. It was considered desirable by the IRRS team that similar provisions on PSR should be implemented for all installations, no matter whether they were BNIs or ICPEs (see Suggestion S26 below). Provisions were in place for waste acceptance and periodic safety reviews of operating waste facilities, e.g. the Centre de l’Aube facility, likewise operated by ANDRA.

The 2006 mission noted that the public has access to substantial amounts of monitoring and discharge data, through national monitoring networks as well as through reports issued by the operators. During the 2006 mission it was also noted that data on critical group doses were not

included in the annual report from ASN. This observation resulted in Recommendation R16, as indicated below.

### **Recommendations and Suggestions from IRRS 2006 Report**

#### RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- R16 **Recommendation:** ASN should consider inclusion of doses to the critical group from Basic Nuclear Installations in its Annual Report as well as descriptions of their meaning in terms of public health protection, and should assess the cause for differences between sites and different operational years.
- S26 **Suggestion:** For coherence and consistence, the periodic review and assessment (PSR) of the radioactive waste management facilities should be considered and included in the proper regulations for all type of facilities operating in the country; no matter if they are INB, ICPE or activities authorized according to Art. L.1333.4 of Code of Health. The PSR should be commensurate with the hazards posed by the installation and should take due account of the magnitude of the waste study, likely period of storage, the preferable use of passive safety features, the potential for degradation during that period and with due consideration of natural site characteristics that could impact performance as geology, hydrology and climate.

### **Changes since the IRRS 2006 Mission**

**Recommendation 16 and Suggestion 26:** With regard to general aspects of review and assessments, most of the observations made at the 2006 missions remain valid. However, there has been progress in certain areas. Concerning PSR, such reviews are mandatory in all facilities under the surveillance of ASN and in the case of ICPEs the Code of Environment contains similar provisions. For the management of TeNORM, which is under ASN mandate, ASN is working on further recommendations. These actions take care of the concerns expressed under suggestion S26.

On the point of public access to discharge/exposure data, the follow-up mission noted that a web-based compilation of monitoring data for public access is under way, opening to the public in January 2010.

Critical group annual dose data (see R16) have been included in ASN Annual Report since 2007, including retrospective data, and the implications of the annual doses in terms of health consequences are explained. ASN has requested IRSN to assess the contributing factors to differences between sites and ASN has requested a report from IRSN on this issue.

### **Findings from the 2009 Follow-up IRRS Mission**

**Suggestion 26 is closed:** the actions result in a coherent system for periodic review of the operation of waste facilities.

**Recommendation 16 is closed on the basis of progress and confidence.** A review of reasons for site-dependent differences in critical group doses, from IRSN, was received during the course of the Mission. The Follow-up IRRS Mission reflects this in a Suggestion, as follows:

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

- (1) **BASIS:** GS-R-1 §3.3(6) states: *In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body: .... (6) shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public.*
- SF3 **Suggestion:** ASN should consider adding an analysis of differences in annual doses from discharges from different nuclear installations, based on the input from IRSN, to ASN Annual Report.

### 4.3 INSPECTION AND ENFORCEMENT

ASN has initiated extensive and comprehensive programmes related to inspection and enforcement at basic nuclear installations (BNIs). BNIs include nuclear power plants, research reactors, and fuel processing facilities. The inspection and enforcement programme ensures that facilities, equipment, and work performance meet all necessary requirements; that relevant documents and instructions are being complied with; persons employed by the operator are appropriately trained and qualified; noncompliances with operating authorizations are complied with within a reasonable time frame; lessons learned are identified and propagated to the regulatory body (but not necessarily to other types of facilities); and the operator is managing safety in a proper and responsible manner. The activities of suppliers and contractors are monitored by observations of ongoing activities and the operator is held responsible for the quality of the material, components, and services provided by the contractor.

The regulatory authority makes it very clear that the operator has the prime responsibility for safe operation of the facility.

#### 4.3.1 BASIC NUCLEAR INSTALLATIONS

##### **INSPECTION**

##### **Considerations and Findings from IRRS 2006**

Inspection programmes are developed and inspections conducted to verify that the operator is in compliance with conditions established in the operating authorizations. Although a number of sources of information were utilized in the development of BNI inspection programmes, it did not appear that results of the Periodic Safety Reviews or operating experience reviews were extensively used in the programme development. ASN does not currently have a developed and documented inspection oversight programme for the human factors, human and organizational performance, and safety culture areas of criteria their mandate. A robust and comprehensive accreditation programme has been developed for inspectors. ASN inspectors develop detailed agendas for inspections and document inspection findings in a readily available manner.

##### **Recommendations and Suggestions from IRRS 2006 Report**

<b>RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION</b>	
S27	<b><u>Suggestion:</u></b> ASN should formalize the way of considering use of the results of periodic safety review, as well as operational experience in the development of BNI inspection programmes.
S28	<b><u>Suggestion:</u></b> ASN should consider a formal periodic assessment of the inspection programme to evaluate its continued effectiveness, including consideration of risk informed insights.
S29	<b><u>Suggestion:</u></b> ASN should further develop guidance for providing inspection oversight of human factors, human and organizational performance, and safety culture areas of their mandate.

##### **Changes since the IRRS 2006 Mission**

**Suggestions 27 and 28:** ASN develops an annual inspection programme for BNIs. This programme is based upon a systematic assessment of available information obtained from ASN directorates, regional offices, and IRSN, and includes operational data, operating experience, and inspection results and observations. This information is compiled into a “monographie”. It is discussed during a general meeting in June of each year during which the priorities of the inspection programme are defined. ASN also develops a specific inspection plan for NPP refueling outages. These plans include inspections of modifications of the NPP that are implemented as a result of the

PSR. In this manner, ASN incorporates PSR results and operating experience into its inspection of NPPs. ASN also produces “monographies” for other nuclear activities, such as transport, radiotherapy, gammagraphy and nuclear medicine. These “monographies” provide the data which could be used for trending and a formal assessment of inspection programme effectiveness. However, such a formal assessment process does not exist.

**Suggestion 29:** ASN has taken steps to enhance its oversight of human factors, human and organizational performance, and safety culture. Inspection guidance applicable for any BNI has been issued. The annual inspection programme provides specific requirements on inspection frequency, which has increased since 2006. ASN has recruited two additional human factors experts in 2007. In addition, all inspectors are required to take a 2-day long training class on human and organizational factors.

**Findings from the 2009 Follow-up IRRS Mission**

**Suggestions 27 and 29 are closed.**

**Suggestion 28 is open:** pending formalization of a process that assesses inspection programme effectiveness.

**ENFORCEMENT**

**Considerations and Findings from IRRS 2006**

Enforcement actions are intended to respond to non-compliances at BNIs. ASN requires the operator to take the necessary actions to correct identified deficiencies, comply with identified non-compliances, and to take actions to prevent recurrence. The inspection programme detects and requires corrective action for repeat non-compliances, and stronger, although not clearly specified, enforcement actions may be taken. ASN relies on inspector skill and IRSN expert advice to determine whether an issue has only “minor safety significance.” Enforcement actions were somewhat informal for lesser significant non-compliances, although the recently enacted TSN 2006 Act provides for clearer authority for sanctions. The enforcement mechanisms and procedures for implementing this new law have yet to be developed in detail. However, the general enforcement philosophy was understood by the inspection staff interviewed.

**Recommendations and Suggestions from IRRS 2006 Report**

**RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION**

- R17 **Recommendation:** ASN should provide guidance to the inspection staff on how to determine the relative seriousness or significance of non-compliances and how to resolve identified issues of minor safety significance, such that an appropriate and consistent level of enforcement action can be applied.
- R18 **Recommendation:** ASN should develop the necessary enforcement tools and implementation guidance to effectively and consistently implement enforcement sanctions commensurate with the seriousness of the non-compliance.

**Changes since the IRRS 2006 Mission**

ASN has provided guidance to the inspection staff on how to determine the relative seriousness or significance of non-compliances and the appropriate enforcement tool to be used in each instance. ASN note ASN/SAN/02 describes a graduated approach for enforcement actions, including the smallest deviations. The note covers BNIs, transportation, pressure vessels, and small scale and medical applications. The approach considers the observed risk for people and the environment and takes into account factors specific to the licensee (history, behavior, repeated nature of the problem), contextual factors, and the nature of the infringements observed (regulations, standards, internal procedures, etc.). Guidance is provided on the appropriate licensee interaction (follow-up

letter, decision, formal notice, etc.) and ASN follow-up inspection activities. Infringements punishable by penal sanctions are transmitted formally to the Public Prosecutor's Office. The note has been used successfully on several recent enforcement actions. An order and several ASN decisions are under development to more fully describe licensee responsibilities and additional ASN notes are planned to cover the full range of ASN controlled activities..

**Findings from the 2009 Followup IRRS Mission**

**Recommendations 17 and 18 are closed on the basis of progress and confidence:** pending the development of notes that are planned to cover the full range of ASN controlled activities (transportation, pressure vessels).

4.3.2 *MEDICAL PRACTICES*

**Considerations and Findings from IRRS 2006**

In planning the annual inspection programme, consideration was given to particular identified needs. This might be from feedback from previous inspection programmes, or advice received from IRSN. In 2006, facilities using X-rays in interventional procedures received particular attention.

Inspections of approved organizations performing the quality controls on medical devices required by the AFSSAPS decisions, were being performed by AFSSAPS. Given the crucial role of these quality controls in the radiation protection of the patient AFSSAPS needed to utilize feedback from ASN inspections.

ASN was developing internal guides for the conduct of inspections in nuclear medicine, radiology, CT scanners, brachytherapy, external beam radiotherapy and blood irradiators. Three types of documents were being developed: "Ordre du Jour", effectively the agenda for the inspection; "Guide pour la conduite d'une inspection", giving in-depth detail for the conduct of the inspection; and "Canevas", giving details for those activities that are under particular study.

**Recommendations and Suggestions from IRRS 2006 Report**

RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION	
S30	<b><u>Suggestion:</u></b> That ASN ensures that AFSSAPS takes note of the findings of ASN inspections in the AFSSAPS processes for approval and inspection of organizations performing the quality controls on medical devices required by the AFSSAPS decisions.
S31	<b><u>Suggestion:</u></b> ASN is urged to complete the inspection documentation to cover all uses of radiation in medical practices (i.e. concerning conventional radiology and brachytherapy).
S32	<b><u>Suggestion:</u></b> That ASN but extends the scope of its radiotherapy inspections to include organizational and human factors as presented in the IAEA Safety Series Report 38.
S33	<b><u>Suggestion:</u></b> That ASN reconsiders the relative merits of inspectors performing technical measurements during a pre-authorization visit.
R19	<b><u>Recommendation:</u></b> That ASN reconsiders the current frequencies for inspection of medical facilities using radiation, taking into account current international standards and good practice, in particular for interventional radiology and radiotherapy.
S34	<b><u>Suggestion:</u></b> ASN should complete the development of formal procedures to analyse inspection findings and to incorporate these findings into the appropriate regulatory processes.
R20	<b><u>Recommendation:</u></b> That ASN develops and implements a formal enforcement policy that covers the use of radiation in medical practices.

**Changes since the IRRS 2006 Mission**

With the experience of several major events in radiotherapy centers ASN has reviewed inspection frequencies and is currently inspecting all 180 radiotherapy installations annually. The inspection programme is tailored to areas of concern, and for 2009 include the safety of staff in radiotherapy centers (after some cases of staff being found in treatment rooms when exposures were made), the degree of physicist support, dose verification procedures (particularly through *in vivo* dosimetry), and analysis of events. Effort is being directed to improve reporting of adverse events, and for the reporting procedures to be harmonized. Enforcement actions taken include suspending licences at 3 radiotherapy centres for non-compliances with the mandatory provision of the presence of a physicist during treatments. Many centres remain non-complying with the mandatory provision of having a physicist during treatments due to the occasional absence of physicists. Inspection reports are placed on ASN web site since July 2008.

**Suggestion 30 is closed on the basis of progress and confidence:** ASN has established a MOU with AFFSAPS relating to approvals and quality controls of radiation emitting medical devices (see also R08). In parallel, ASN has proposed an amendment of the Public Health Code (Note of 3 July 2008).

**Suggestion 31 is closed on the basis of progress and confidence:** ASN has published a guide for conventional radiology inspections, and is drafting an inspection guide for brachytherapy. This will be trialled before being finalised.

**Suggestion 32 is closed:** Organisational and other factors are included in current inspection guidance.

**Suggestion 33 is closed on the basis of progress and confidence:** Documentation on inspection in medical practices, including performing technical measurements during a pre-authorization visit is to be revised soon.

**Recommendation 19 is closed:** The frequency for radiotherapy inspections has been modified to annually according to ASN/INS/02D (1/4/2008) and for interventional radiology to 3 years (ASN-DEP-DEU-No.: 0707-2008, 26 September).

**Recommendation 20 is closed on the basis of progress and confidence:** ASN/SAN/02 details enforcement policy covering all areas (including small-scale and medical activities) and guidance documents with practical examples are being released. An additional ASN note, to cover medical practices has been drafted and is pending approval.

**Suggestion 34 is closed:** ASN has developed a process to compile and synthesize inspection information and related operational data into a document referred to as a monographe. Monographes have been used for many years for NPPs. Their use has been expanded into other BNIs and small scale nuclear activities. The monographe is one source of information that is considered during the development of the annual inspection programme. Inspection priorities, inspection procedure revisions, and inspection frequency are discussed and appropriate changes are determined. In this manner, inspection findings are incorporated into the regulatory process.

**Finding of the 2009 follow-up IRRS mission**

**Recommendation 19 and suggestions 32 and 34 are closed.**

**Suggestions 30, 31, 33 and Recommendation 20 are closed on the basis of progress and confidence.**

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION**

GF8 **Good Practice:** The placement of radiotherapy practice inspection reports on ASN website is a powerful enforcement tool.

### 4.3.3 INDUSTRIAL AND RESEARCH PRACTICES

#### Considerations and Findings from IRRS 2006

ASN performs inspections of industrial and research practices using radiation, primarily through the DSNRs. It should be noted that the scope of inspections includes veterinary practices: both diagnostic and therapy uses of radioactive sources in animals (namely horses, cats and dogs), and the use of electrical generators in veterinary applications, mainly in radiography studies. Inspection and enforcement activities verify and ensure compliance with all requirements. The assessment of the competence of operator's contractors is not a function of the DSNR, but the safety-related services provided to the operator must be carried out by approved organizations. The inspectors inform the operator's counterpart at the end of the inspection of any identified good practices and corrections required for detected deficiencies and deviations. After the inspection a follow-up letter is sent setting out a time period of two months, within which the licensee must respond with a proposed corrective action plan for the items of non-compliance. For urgent issues of non-compliance, ASN requests immediate action, plus post-inspection verification at the site. Lessons learned are disseminated inside ASN and to operators by means of the internet, e-mails and letters. The prime responsibility for safety of the operator is not diminished by the regulatory inspections carried out by the DSNR. ASN performs both announced and unannounced inspections of industrial and research practices using radiation. ASN also performs inspections as the result of an abnormal occurrence in industrial and research practices using radiation. Inspectors do not have the authority for taking on the spot enforcement actions, they must inform ASN authorities. There is written guidance, however, a more detailed guide or procedure for inspectors detailing how to proceed accordingly is necessary.

#### Recommendations and Suggestions from IRRS 2006 Report

##### **RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION**

R21      **Recommendation:** ASN should prepare more detailed guidance or procedures addressed to inspectors establishing in writing how they must proceed.

#### Changes since the IRRS 2006 Mission

ASN has revised its internal guidance for the inspection programme (ASN/INS/03), in part to reflect the development of the quality assurance system of ASN. Detailed instructions for inspectors are provided in INTERNE/INS/DEU/031, which replaced ASN/INS/02a. It provides guidance on inspection objectives and inspector behavior, and also advice on how inspectors should proceed in response to many situations that might develop during an inspection. Templates are provided to enhance consistency of inspection documentation. ASN has established in its annual plan an approach to enhance and develop additional detailed guidance for inspectors. For instance, inspection guidance about human factors was released in January 2009. While detailed guidance has existed for many years for the BNIs, the responsibility for radiation protection is fairly new and additional detailed guidance is needed and must be developed. The annual plan should address this need.

#### Findings from the 2009 Follow-up IRRS Mission

**Recommendation 21 is closed on the basis of progress and confidence:** in view of the schedule for completion in 2009.

### 4.3.4 WASTE FACILITIES, DECOMMISSIONING AND REMEDIATION

#### Considerations and Findings from IRRS 2006

The inspection and enforcement in the area of management of gaseous, liquid and solid radioactive waste is part of the general inspection programmes either these are developed for BNIs or ICPEs, or

whether they are developed for facilities that are in operation or being decommissioned. Also the enforcement procedures are the same. The 2006 mission report should be consulted for a fuller account on this matter.

### **Recommendations and Suggestions from IRRS 2006 Report**

*There were no recommendations or suggestions made during the 2006 IRRS mission in this area*

### **Changes since the IRRS 2006 Mission**

Changes to the procedures would be in harmony with those described in earlier sections for BNIs, if any, although this specific point was not checked, for waste facilities, during the Follow-up IRRS Mission. Observations made during the 2006 mission remain largely valid

### **Findings from the 2009 Follow-up Mission**

No recommendations, Suggestions or Good Practises from the Follow-up Mission

## **4.4 REGULATIONS AND GUIDES**

### **Considerations and Findings from IRRS 2006**

In 2006, ASN was planning to further develop regulations and guides for NPPs consistent with the Western Europe Nuclear Regulators Association (WENRA) “Harmonisation of Reactor Safety in WENRA Countries” Reference Standards. The WENRA project was viewed as a systematic approach to systematize the review of present regulations and guides for NPPs and was expected to produce a consistent set of requirements and guides. However, the team identified the need to perform also a systematic review of regulations and guides for the facilities and activities outside of the NPP regulatory envelope.

It was also noted that ASN had not required incorporation of all the requirements of GS-R-3 “The Management System at Facilities and Activities” in the requirements for BNIs. GS-R-3, published in 2006, describes the characteristics of a comprehensive management system based on safety as its fundamental principle. It was noted that the Order of August 10<sup>th</sup>, 1984 concerning Quality of Design, Construction and Operation of BNIs contains requirements that address some aspects of management systems.

### **Recommendations and Suggestions from IRRS 2006 Report**

#### **RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION**

- R22 **Recommendation:** ASN should undertake a project to review in a systematic way the present requirements and guidance for facilities and activities other than NPP, in order to produce a more consistent assembly of regulations.
- R23 **Recommendation:** ASN should issue a generic requirement to facilities and activities to establish a management system, graded according to the safety significance and complexity of the facility and/or activity.

### **Changes since the IRRS 2006 Mission**

**Recommendation R22:** In 2007, ASN started a project to produce a consistent set of regulations for all BNIs based largely on the WENRA Reference Levels and the applicable IAEA Safety Standards (see Chapter 2 for more discussion). An important step was the development of a procedural decree that was issued in November of 2007 (Decree 2007-1557) that covers the basic nuclear installations (BNIs) and the oversight of the transport of radioactive materials with respect to nuclear safety. This decree covers:

- Application requirements for a new BNI
- Requirements for the Preliminary Safety Case for the BNI

- Commissioning Requirements for new BNIs
- Authorization process for modifications to BNIs
- Periodic Safety Review requirements for BNIs
- Requirements for Final Shutdown and Decommissioning of a BNI
- Requirements specific to radioactive waste disposal installations
- Policing measures and Penalties
- Provisions concerning pressure vessels in BNIs and
- Provisions concerning the transport of radioactive materials.

The decree establishes the regulatory framework for consistent regulations for all BNIs. In conjunction with the work on the Procedural Decree, ASN established an action plan to produce a consistent set of technical regulations (*Plan d'action pour la mise en œuvre du nouveau régime des INB*). The action plan covers all safety issues including waste management and decommissioning. ASN is well advanced in drafting a key document in the plan, a Ministerial Order that defines high-level requirements in the areas of Safety Management, Nuclear Safety, Environmental Protection, Waste Management, Emergency Response, Event Reporting and Nuclear Pressure Equipment. This will formalize a graded approach to BNI requirements consistent with the risks posed by the facilities. ASN has also started to draft other documents required by the plan.

**Recommendation R23:** As mentioned above, generic requirements for licensees to have management system have been included in a draft Ministerial Order. The Ministerial Order also includes a graded approach for requirements. This is an important first step but ASN has to continue the work on the lower tier documents that explicitly address the requirements of GS-R-3. Such documents are part of the action plan for the BNI regulatory regime.

#### **Findings from the 2009 IRRS Follow-up Mission**

Development of the action plan for a consistent set of BNI regulations **completes Recommendation R22**. The team suggests that ASN continues to implement this action plan in a timely manner. CLOSED

The draft Ministerial Order includes the generic approach to management systems for BNIs and progress is advanced enough for **the IRRS team to conclude that recommendation R23 is complete**. ASN is encouraged to finalize this Ministerial Order as soon as practicable and to develop the supporting lower tier documents on management systems.

#### **No Recommendations, Suggestions or Good Practices from the Follow-up Mission.**

##### *4.4.1. NUCLEAR INSTALLATIONS*

#### **Considerations and Findings from IRRS 2006**

TSN Law 2006-686 established formally the requirement for a PSR for all nuclear installations (BNIs) and allows ASN to impose additional safety prescriptions to licensees that already hold an authorization thereby increasing the safety level of the installation. ASN had been requiring PSRs for most facilities through letter to the licensees. These letters defined the scope, content and process of PSR.

ASN had also issued letters to all nuclear facilities containing the technical requirements that shall fulfil the process of modifications. The letters included the definition of the rating of modifications according to the safety significance of the modification and establishes the process for its authorization taking into account that rating, as well as what information to send to ASN regarding the modification.

While ASN had developed appropriate guidance for development of PSAs (FSR 2002-1 “Development and Utilisation of Probabilistic Safety Assessment”) for Pressurised Water Reactors, there was no requirement perform a PSA. ASN requested a PSA, with a given scope, for each NPP in the letter sent to each licensee about the scope of each Periodical Safety Review (PSR). For nuclear installations other than NPP, PSAs were not uniformly requested.

***Recommendations and Suggestions from IRRS 2006 Report***

**RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION**

- S35 **Suggestion:** That the scope, content and process of PSR, currently reflected in part in direct letters addressed by ASN to the utilities be described in an appropriate requirement or guidance.
- R24 **Recommendation:** ASN should formalize through appropriate guidance the spelling out of acceptable criteria for the process of modifications.
- S36 **Suggestion:** A general policy for the utilization of PSA or probabilistic studies, as applicable with a graded approach, should be established at nuclear installations and the corresponding guidance should be elaborated and published.

***Changes since the IRRS 2006 Mission***

**Suggestion 35 is closed:** The Article 29.III of the Law 2006-686 of TSN establishes the duty for BNI to carry out a decennial periodical safety review taking into account as much as possible the present standards required to new BNI and the best international practices. In other words, it is the licensee who has to present its report to ASN and ASN assesses such report.

The Article 24 of the Decree 2007-1557 says that ASN can specify in a decision the conditions for the performance of PSR and the issues to be covered in the licensee report.

The content of the PSR report to be submitted by the licensee is to be specified at an ASN decision, included in the regulatory program of standards elaboration to meet IAEA and WENRA. The draft decision, shown to the team, has been already reviewed by the COREL (Review committee for all standards). The draft asks for two main contents of the report, one to examine the conformity of the BNI, and the another one to reassess its safety, in light of the state of the art: new standards and operational experience (French and international) as well as the experience of the installation operation. During the PSR, it has to be concluded which are the modifications to implement as a consequence of the review performed.

The team concluded that the suggestion has been adequately addressed by ASN, the new standard is going forward at an appropriate pace, and ASN has demonstrated a strong commitment to publish the standard in a reasonable time.

**Recommendation R24 is closed on the basis of progress and confidence:** In 2006, the process for approval of modifications to BNIs or the authorization decree for a BNI was only defined in letters from ASN to the licensees. ASN has since taken a number of steps to define the modification process in regulation. The Procedural Decree (2007-1557) defines completely the process and formalizes the classification of modifications into major, significant, minor and non-safety significant. The non-significant modifications can be handled entirely by the licensees.

For major modifications, as defined in Article 31 of the decree (for example, a change in maximum capacity of a facility or the addition of a new BNI within the perimeter of an existing installation), the licensee must apply to the appropriate Ministers and a Decree is required to approve the modifications. ASN coordinates the review of these modification applications and drafts the decree.

Modifications that do not meet the definition of major are handled in a different manner under the Procedural Decree. The operator must notify ASN of all other proposed modification at least six-months prior to the planned modification. Unlike the normal process under French law, the

Procedural Decree states that these modifications can be considered as approved if ASN does not respond within the six months. ASN classifies all these modifications by safety significance into significant or minor. This allows ASN to concentrate its efforts on safety significant modifications for which it can inform the operator that further review time (up to an additional six months) is required.

Article 27 of the Decree states that for those modifications that are minor, the licensee does not need to notify, as long as they have the appropriate internal controls. ASN has published a decision (2008-DC-0106) that details the requirements for these internal controls. It then must approve the controls for an individual BNI prior to the licensee assuming control for minor modifications. Discussions for use of internal authorizations are well advanced between ASN and CEA for research reactors and research facilities in general, and there has been interest from Areva for use in its fuel cycle facilities. To date, there have not been conclusive discussions with EdF on internal authorizations for NPPs.

ASN has made significant progress on the Modification Process and the IRRS team considers that Recommendation R24 can be closed.

**Suggestion 36 is open:** ASN is now developing an internal policy on the utilization of PSA in regulation, although it is still a working document (“Utilization of PSA – v3”, 17/12/2008). The draft policy on the PSA utilization is in line with the WENRA’s policy (“PSA Explanatory Note”, WENRA Reactor Harmonization Working Group, March 2007), which clearly says that “the safety of nuclear power plants shall rely essentially on deterministic design based on the concept of defense in depth” and that “PSA shall be used to complement the conventional deterministic analysis”, although it is recognizing the usefulness of the insights obtained by PSA.

ASN working document mentions possible usage of PSA related to regulation. For example, EdF will show relative safety importance of proposed modifications based on the PSA results in the course of the next PSR, in order to demonstrate the adequacy of their selection; however, ASN has accepted this proposal in the condition that EdF considers that before establishing this process, they develop a complete PSA, e.g., a PSA level 2 and PSA for external events. IRSN is currently performing accident precursor study for selected events, with its own models.

The working document also says that “the probabilistic analysis cannot be used by the licensee to refuse any counter measure required by the deterministic approach”. Although the document is subject to review and revision from now on, this description is adequate since PSA results are insights and deterministic analyses are rules and that insights never override rules. The IRRS team agrees with the draft ASN policy on the utilization of PSA. However, the team was informed of no development to elaborate guidance for PSA.

#### *Findings from the 2009 follow-up IRSS Mission*

**Suggestion 35 is closed:** is referred to content and process of PSR. The team concluded that the suggestion has been adequately addressed by ASN, the new standard is going forward at an appropriate pace, and ASN has demonstrated a strong commitment to publish the standard in a reasonable time. Therefore, the team considers the Suggestion fulfilled. **closed**

**ASN has made significant progress on the Modification Process and the IRRS team considers that Recommendation R24 can be closed.** The IRRS team suggests that ASN continue to work with all operators implement internal authorizations.

**Suggestion 36 is open** is related to general policy and guidance of utilization of PSA. The team has found that, although a draft policy has been elaborated, no project is still in place to elaborate guidance for PSA. So this suggestion is still open.

#### 4.4.2 NUCLEAR POWER PLANTS (NPP)

Recommendations and Suggestions from IRRS 2006 Report

RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION	
S37	<b>Suggestion:</b> ASN should complete its present process of producing regulations and guides on analysis of operational experience.
S38	<b>Suggestion:</b> That what is presently requested to the operating NPP regarding the severe accident is described in an appropriate requirement or guidance.

Changes since the IRRS 2006 Mission

**Suggestion 37 is open:** ASN exhibited the draft of a BNI Ministerial Order aimed at regulating BNI. The chapter 2.3 of the draft is titled “Management of events and feedback of experience” deals with the reportable events, how to analyse them and how to report to ASN. The Article 2.16 of chapter 2.3 says that the licensees shall collect and analyse available information of experiences of other similar industries, including foreign industries, susceptible to provide lessons learnt for the integral safety of the installation.

Once this Ministerial Order is published, it will provide appropriate ground to ASN for elaborating and specifying further the requirements on the treatment of OE. However, the team was informed that ASN has no plans at the present time to elaborate any Decision or guidance on this specific subject.

**Suggestion 38 is closed:** Severe Accident Countermeasures for Existing NPPs: The operator carries out PSR for its existing plants every 10 years and, as mentioned in the text for S16, the Safety Re-evaluation is one of the key components of the PSR. The operator examines whether the plant is safe enough compared with modern and, if some discrepancies are found, the operator is obliged to modify its plants to satisfy the authorization criteria for modern plants as much as feasible.

In France, EPR was proposed and its safety design, including some provisions against severe accidents, was already examined and authorized by ASN. It means that the operator must adopt some severe accident counter measures, including accident management guidelines, in PSR as much as reasonably practicable.

Findings from the 2009 follow-up IRSS Mission

**Suggestion 37** relates with the need for ASN to complete its present process of producing regulations and guides on analysis of operational experience. The team was informed that ASN has no plans at the present time to elaborate any Decision or guidance on this matter. Consequently, the team considers that this suggestion is still **open**.

**Suggestion 38** relates with the need of guidance as to how undertaking the severe accident issue in the existing plants. Operating plants will have to examine the requirements on severe accident of new plants, such as the EPR in the framework of PSR, as requested by the present regulation, therefore, the team considers this suggestion adequately addressed. **CLOSED**

4.4.3 *MEDICAL PRACTICES*

Considerations and Findings from IRRS 2006

The set of regulations, orders, decisions and circulars was somewhat fragmented. In the context of medical exposures, the regulations in France establish a framework for ministerial orders and decisions, and these provide the detailed technical requirements rather than having these incorporated into individual authorizations.

ASN was continuing preparation of guidance for users of radiation in medical practices on how to comply with the regulatory requirements.

Recommendations and Suggestions from IRRS 2006 Report

## RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- S39 **Suggestion:** ASN should use its new powers to issue a set of technical decisions, after appropriate consultation and review, to give a coherent and harmonized set of regulatory requirements for authorized and declared practices using radiation for medical exposures based on current international standards such as those of the IAEA.
- R25 **Recommendation:** That ASN completes the development of guidance on regulatory compliance for all areas of radiation use in medical practices. That ASN should also consider the IAEA safety standards and guidance when developing regulations and guides.

### Changes since the IRRS 2006 Mission

**Suggestion 39 is closed on the basis of progress and confidence:** (refer also to S02): ASN is progressing on a set of regulatory decisions.

“Décisions fournisseur n° 2008-DC-0108 et 109 du 19 août 2008 et arrêtés d'homologation” has been issued relating to cyclotrons, distribution, import/export of sealed and unsealed sources.

**Recommendation 25:** ASN has developed or contributed to a set of guides on occupational exposures due to medical practices. Since 2006 the following guides have been published:

- \* Présentation des principales dispositions réglementaires de radioprotection applicables en radiologie médicale et dentaire (Edition 2007 MàJ octobre 2008)
- \* Médecine et rayonnements ionisants: fiche d'aide à l'analyse des risques en curiethérapie (INRS TC119 2008)
- \* Radioprotection médicale. Curiothérapie bas débit non pulsé (INRS ED4248 2008)
- \* Analyse des risques en radiothérapie externe (INRS TC114 - 2007)
- \* Médecine et rayonnements ionisants: fiche d'aide à l'analyse des risques en radiothérapie et textes applicables (INR TC106 - 2006)

These guides take into account IAEA standards.

### Finding of the 2009 follow-up IRRS mission

**Recommendation 25 is closed.**

**Suggestion 39 is closed on the basis of progress and confidence.**

The regulations and guides for medical practices are providing for effective controls for radiation safety and reflect a mature regulatory control programme.

#### 4.4.4 INDUSTRIAL AND RESEARCH PRACTICES

##### Recommendations and Suggestions from IRRS 2006 Report

*There were no recommendations or suggestions made during the 2006 IRRS mission in this area*

#### 4.4.5 WASTE FACILITIES, DECOMMISSIONING AND REMEDIATION

##### Considerations and Findings from IRRS 2006

In the field of radioactive waste management, the operators define their general strategy and programmes which are periodically reviewed and assessed by ASN (and its technical supports). The operators also produce a ‘waste study’ which is submitted to ASN for review and approval. The nuclear operators are responsible for the environmental protection during all stages of their nuclear installations and, among them, of their predisposal facilities (treatment, storage, etc.).

Notably, the operator of a BNI has to comply with the following requirements:

- the procedures for authorization of creation of a facility, including a public inquiry procedure. The technical dossier includes an impact study and a safety assessment. In the case of releases, a document is submitted to the European Commission under the terms of Article 37 of the Euratom Treaty;
- the technical requirements imposed on the operator and issued by ASN as an accompaniment to the authorization decree;
- the procedures for the commissioning of the installation;
- a periodic revision of the safety assessment of the installation (to be submitted to ASN);
- the procedures for the decommissioning of the installation;
- declaration of incidents; and,
- the production of an annual report transmitted to the Local Information and Follow-up Committee and the High Committee for Transparency and Information on Nuclear Safety required by the recent law.

The review in 2006 had the opportunity to review the recently adopted 2006 Programme Act<sup>1</sup>, which, *inter alia*, stipulates that a ‘National management plan for radioactive materials and waste’ should be developed every third year. The Programme Act covers numerous other issues, relevant to regulations and guides, and followed up in this report.

A number of further observations were made, many of them still relevant. However, with the implementation of the new Programme Act, also a number of earlier provisions may have become obsolete. It was observed that clarifications were desirable in the areas of decommissioning and remediation. In the specific case of clearance, it was observed that the concept is not implemented in France in terms of nuclide-specific clearance levels. Material considered contaminated is treated as waste and its final disposal takes place according to the established procedures for waste, e.g. in the repository for very low level waste located in Morvilliers and operated by ANDRA. This approach is more restrictive than the approach specified in IAEA Safety Standards. The 2006 IRRS Mission suggested that this should be openly communicated so that all interested parties know of the stringent measures taken to protect the public or environment from radiological risks associated with such releases.

In the case of areas contaminated by past practices, a Circular of the Ministry for the Environment of 1997 stipulates that the Prefet is responsible for the management of polluted sites. The 2006 mission noted, with regard to remediation, that there were provisions in place for establishing the necessary restrictions and controls for the use and/or access to areas before, during and – if necessary – after remediation. A graded approach to assessments and programmes for control is employed. It was noted that there were no specified safety criteria for remediation of contaminated sites, including required conditions at the end point of in remediation.

The main radiological safety criterion for both a near surface and a geological repository is the dose received by the public. The dose is constrained to 0.25 mSv/year extended exposure associated with events which are certain or highly probable for a period of at least 10,000 years. Beyond this period of stability of the geological barrier, the same dose constraints for the public (0.25 mSv/year) is used as a reference value.

### **Recommendations and Suggestions from IRRS 2006 Report**

## RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

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<sup>1</sup> The 2006 Programme Act on the Sustainable Management of Radioactive Materials and Wastes

## RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

- R26 **Recommendation:** ASN should be involved at an appropriate level in the general revision of the regulation on polluted sites undertaken by the Ministry of the Environment that should provide a specific regulation on the remediation of polluted sites contaminated with radioactive materials. The new regulation should follow the recommendations of the International Standards. In this process it will be important to consider that before the formal termination of the remediation programme and the release from further responsibilities of the organization responsible for implementing the remedial measures, compliance with initial criteria shall be verified and the termination should be routinely subject to the approval of by the regulatory authorities.
- R27 **Recommendation:** ASN should coordinate with the Ministry of Environment the establishment of common approach for all disposal facilities that may dispose of radioactive waste general safety requirements and regulatory regime. In this regard the regulations should be developed or reviewed to be approved and implemented according to a schedule set up by the National Plan for the Management on Radioactive Material and Waste.
- S40 **Suggestion:** ASN should within the framework of the new waste law consider the inclusion of a radioactive waste classification scheme (or schemes) or at least the basis for it in the radioactive waste management regulation. This classification scheme should consider the National Plan on Radioactive Waste Management actually in elaboration.
- R28 **Recommendation:** The dose constraint principle is considered in the regulations for the geologic disposal. ASN should consider extending this concept to other areas and practices in order to communicate that the derivation of limits, and the optimization procedure, originates in a constraint that has been derived to safeguard that the dose limit of 1 mSv will not be exceeded.
- R29 **Recommendation:** ASN should coordinate with the Ministry of Environment the regulation of radioactive waste management to ensure the necessary consistency between the different regulations, whether they are issued by ASN or the ministry for the environment for ICPEs. It is recommended to include all activities and facilities present in the country and not only BNIs. Probably this may be organized in the framework of the National Plan for the Management of Radioactive Material and Waste.
- S41 **Suggestion:** ASN should consider to issue in a short term a regulation covering the design and construction of a radioactive waste storage facility, the likely period of storage, the preferable use of passive safety features, the potential for degradation during that period and with due consideration of natural site characteristics that could impact performance as geology, hydrology and climate.
- R30 **Recommendation:** ASN (in coordination with the Ministry of Environment) should establish generic reference (intervention) level, or generic safety criteria for aiding decisions on remediation and allowing to the establishment of the optimum strategy for facilities other than BNIs.
- S42 **Suggestion:** ASN should develop the regulations needed to support the decommissioning process from the design stage till the shutdown and decommissioning of different facilities.
- S43 **Suggestion:** ASN should clarify the policy on clearance, and communicate to interested parties including the public that, although declassification does occur, this is done whilst applying highly restrictive approaches and guidelines to safeguard public health.

### Changes since the IRRS 2006 Mission

**Recommendation 28:** The follow-up mission discussed the issues of application of best available technique (BAT) for discharge limitation and optimisation in the absence of dose constraints, as well as the reporting of critical doses to the public. Requirements on optimisation and application of BAT are specified in the Order of 26 November 1999<sup>2</sup>. It was also noted, as during the 2006 mission, that for waste disposal, a dose constraint of 0.25 mSv annually applies, at least in the short to medium range time frames. The 1 mSv annual dose limit for all exposures is also valid in all cases of planned exposure situations.

On the issue of BAT for discharge limitation, there is some national (e.g. among different generations of EDF reactors) as well as international benchmarking. The recurrent reporting to the OSPAR Convention for the protection of the marine environment in the North-east Atlantic is an external driver as well as an international benchmark. Discharge limits are periodically reviewed as a part of the periodic safety report (PSR) and amended as appropriate. A review of the discharge authorisations is ongoing and should reach completion in 2012. France considers itself complying with the strategy for radioactive substances drawn up under the OSPAR Convention, and reported compliance with the PARCOM Recommendation 91/4<sup>3</sup> in 2006.

In the opinion of ASN, issuance of formal dose constraints to guide optimisation will not have any further effect on discharge limitation, and would be difficult to communicate with both the public and the industry, as internationally agreed constraints (0.3 mSv annually or less) are far above dose rates achievable through discharge limitation. A performance-based approach including BAT as a criterion is effective; however, it does not preclude definitions of prospective 'constraints' in the planning stage for new facilities – and as used for e.g. storage and disposal facilities as already stated above.

On the basis of the reasoning above, it can be concluded that the introduction of constraints in the case of discharges from operational BNIs would probably serve little purpose, and that the same effect in terms of discharge limitation is achieved although through different means. The optimisation principle is still used - and strengthened by application of BAT. Furthermore, constraints *are* actually applied in prospective regulation.

**Recommendations 27 and 29; Suggestions 40, 41 and 43:** – *information relevant to the National Management Plan for Radioactive Materials and Waste*

As stated in the survey of the 2006 mission report above, the Programme Act stipulates that a National Management Plan for Radioactive Materials and Waste shall be developed at three-year intervals:

Article 6 I. 2<sup>nd</sup> par: A national plan for the management of radioactive materials and wastes appraises the existing management modes of radioactive materials and wastes, identifies the foreseeable needs for storage or disposal installations, states the necessary capabilities for these installations and the storage timeframes and, for radioactive wastes which are not yet the subject of a definitive management code, determines the aims to be reached.”

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<sup>2</sup> For gaseous and liquid discharges in Articles 8 and 15, respectively, of the Order of 26 November 1999 specifying the general technical requirements concerning the limits and the procedures for basic nuclear installations intake and discharge subject to authorisation.

<sup>3</sup> On the use of BAT to limit discharges of radioactive substances, now under the OSPAR Convention; Rapport national française de mise en œuvre de la Recommandation PARCOM 91/4 sur les rejets radioactifs, OSPAR Commission, 2006

The plan is to be followed by a Decree specifying actions to be taken. The first National Plan<sup>4</sup> covered the years 2007 – 2009, and the second plan, covering the years 2010 – 2012 is currently being finalised.

Work on the National Plan commenced in 2003 and was a collaborative effort involving representatives of the government, waste producers, ANDRA, IRSN and environmental protection organisations, and was led by ASN. The work carried out in these constellations was also important in developing the Programme Act of 2006.

The plan covers all major categories of waste either they are produced in BNIs or in ICPEs, defines the necessary research, considers monitoring, describes waste classification, and for many areas suggests a way forward. The French approach to ‘clearance’ is established and has been further elaborated in a memorandum on acceptable complete cleanup methodologies<sup>5</sup>. From the point of view of putting the actions covered by the plan into force, Decree 2008-357<sup>6</sup> specifies the various actions and reports requested from ANDRA and other organisations, as well as confirms the waste classification scheme drawn up in the National Plan. Likewise, internal documents within ASN specify the different regulatory documents that are required, *inter alia* in the waste management area<sup>7</sup>.

The 2006 IRRS Mission issued two recommendations (R27 and R29) as well as two Suggestions (S40 and S43) that are of direct relevance to the National Plan. With regard to collaboration between several organisations (including the ministerial level and ASN) in drawing up the plan, implementation through decrees and internal documents, comprehensiveness, the waste classification scheme contained in it, and the explanation of the French approach to the clearance concept, the follow-up mission considers those suggestions and recommendations implemented.

As regards suggestion S41, the issues raised are covered by the national plan and the internal planning documents on development on regulations, referred to earlier. It would appear that suggestion 41 is now implemented from the waste management perspective.

**Recommendations 26 and 30, and Suggestion 42:** Since the 2006 mission, a number of developments have taken place governing the process of decommissioning. The procedural basis for decommissioning activities of BNIs is laid out in the Decree 2007-1557<sup>8</sup>, which includes, *inter alia*, provisions on timing, content and communication of information relevant to a decommissioning authorisation.

ASN has subsequently developed guidelines for final shut-down, dismantling and declassification<sup>9</sup>, also aided by technical specifications on clearance (as mentioned earlier), and by guidelines on remediation as described below.

For the control and safe remediation of polluted sites, ASN has in collaboration with relevant ministries and other organisations drawn up a procedural guidance<sup>10</sup> that enables local decision making (at the level of the Prefet) to take place on a case-by-case basis with the support of regional and central authorities, including ASN. ANDRA has the responsibility for managing the sites and

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<sup>4</sup> National management plan for radioactive materials and waste 2007 – 2009, “From the national inventory of radioactive waste and recoverable materials to an assessment and forward perspective of the long term management channels for radioactive waste in France”.

<sup>5</sup> Memorandum SD3-DEM-02.

<sup>6</sup> Décret n° 2008-357 du 16 avril 2008 pris pour l’application de l’article L.542-1-2 du code l’environnement et fixants les prescriptions relatives au Plan national de gestion des matières et des déchets radioactifs.

<sup>7</sup> E.g. Plan d’action pour la mise en œuvre du nouveau régime des INB, 17 July, 2008.

<sup>8</sup> Décret no 2007 – 1557 du 2 novembre 2007 relatif aux installations nucléaires de base et au contrôle, en matière de sûreté nucléaire, du transport de substances radioactives.

<sup>9</sup> Guide relatif à la mise à l’arrêt définitif, au démantèlement et au déclassement des installations nucléaires de base en France, Guide n° 2, February 2009.

<sup>10</sup> Prise en charge de certains déchets radioactifs et de sites de pollution radioactive. 17 Nov 2008.

remediation actions when the responsible party can not be identified or held responsible, and receives funding for these activities on an annual basis, depending on the prioritisation of specific projects. Other organisations may carry out the remedial actions under the supervision of ANDRA.

ASN has, jointly with the Ministry of Environment, requested more technical guidance to be developed by IRSN that would also be harmonised with guidance for chemically contaminated sites. The guidance is mainly relevant to industrial sites but may also serve as a reference for 'orphan' sites.

The development since 2006 takes care of several of the issues pointed out by the 2006 Mission, as described in recommendations R26 and R30, as well as suggestion S42. The coordination between ASN and other concerned parties in the area of remediation (relevant to suggestion S49) is further considered in Chapter 6 of this report, as a basis for identification of a good practice.

### *Findings from the 2009 Follow-up Mission*

**Recommendation 28 is no longer relevant and therefore closed.** Whereas generic constraints are not defined for e.g. NPPs they are used in prospective regulation for waste facilities. Discharge limitation from operating facilities takes place through implementation of optimisation (but not against a formal constraint) and through implementation of Best Available Techniques. This approach is efficient and the introduction of constraints would have no further effect.

**Recommendations 27 and 29, and Suggestions 40, 41 and 43 are closed.** ASN has implemented these through the National management Plan for Radioactive Materials and Waste, and by action plans developed by ASN on the basis of the National Plan and relevant Decrees.

**Recommendations 26 and 30, and Suggestion 42 are closed on the basis of progress and confidence.** Additional technical guidance has been requested from IRSN, and which is currently pending, and should be implemented. While R 26, R30 and S42 thus have been implemented from the point of view of the 2009 Follow-up Mission, the need to implement technical guidance in the suggestion outlined below:

#### **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION**

- (1) **BASIS:** GS-R-1 §6.15 states *“The regulatory body shall provide any necessary input to the intervention process. Such input may be advice to the government or regulatory control of intervention activities”*.
  - (2) **BASIS:** GS-R-1 §3.14 states *“Nuclear and radiation facilities and activities will give rise to some radiation exposure. This can be safely controlled by design and operational measures. However, circumstances may arise in which intervention is needed to reduce or avert exposure or potential exposure to radiation arising from an accident or from a discontinued or inadequately controlled practice, or to radiation occurring naturally at unusually high levels. In such situations the government shall appoint organizations to be responsible for making the necessary arrangements for intervention to ensure that remedial action is taken to protect the public, workers and the environment. The intervening organization shall have the necessary resources and authority to fulfil its function”*.
  - (3) **BASIS:** WS-R-3 §5.6 states *“Before the formal termination of the remediation programme and the release from further responsibilities of the organization responsible for implementing the remedial measures, compliance with criteria shall be verified and the termination shall be subject to the approval of the regulatory body”*
- SF4 **Suggestion:** ASN, in collaboration with relevant ministries and other organisations concerned, should implement the technical guidance on remediation of polluted or contaminated sites that is currently being developed by IRSN, to assist regional authorities and ANDRA in remedial actions.

#### **4.4.6. OCCUPATIONAL RADIATION PROTECTION**

##### **Considerations and Findings from IRRS 2006**

The Labour Code sets out provisions relating to the protection of workers against the risks of exposure to ionizing radiation. These are defined in compliance with the general principles of radiation protection of persons laid down in Public Health Code. The Labour Code regulations apply to persons exposed in both practice and intervention situations and place primary responsibility for occupational protection on the head of the establishment having the authorization to use radiation. This includes responsibility for the application of preventive measures necessary for the protection of personnel, including the supply, maintenance and monitoring of personal

protective apparatus and equipment, and individual exposure measuring equipment. The provisions of the Labour Code on occupational radiation protection are generally consistent with the requirements of the BSS (Appendix I). However, they differed in some respects.

**Recommendations and Suggestions from IRRS 2006 Report**

**RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION**

- |     |   |
|-----|---|
| S44 | <b><u>Suggestion:</u></b> Consideration should be given in guidance and codes of practice to the use of constraints, which are practice-specific.   |
| R31 | <b><u>Recommendation:</u></b> ASN should consider a requirement for authorized establishments to develop quality assurance systems.   |
| R32 | <b><u>Recommendation:</u></b> ASN should introduce regulatory changes so that passive dosimeter personal dosimetry results are promptly communicated directly to monitored individuals, ASN, and employers. |

**Changes since the IRRS 2006 Mission**

**Recommendation 31:** ASN has selected a step by step process to establish quality assurance systems within different oversight areas. In 2008 ASN issued a decision to enforce a quality assurance system in radiotherapy facilities (ASN decision n° 2008-DC-0103 of July 1<sup>st</sup>, 2008). This decision is supplemented by two guides about quality assurance and risk analysis adapted for the specific conditions in radiotherapy. Further ASN intends to prepare a comparable decision for users of high activity sources.

**Recommendation 32:** ASN provided a copy of of Article R.4452-19 which requires immediate reporting of worker exposures beyond regulatory limits to the employer and, when appropriate, to ASN. ASN provided a copy of Article R. 4453-26 regarding reporting of workers exposures to the worker and occupational health doctor.

**Suggestion 44:** ASN has determined that the dose constraint approach is included in the regulations through the optimization principle.

**Findings of the 2009 follow-up IRRS Mission**

**Recommendation 31 and 32 is closed.**

**Suggestion 44 is closed.**

## **Policy Discussion on Exposures to ionizing radiations in medical radiology: a world priority in radiation protection**

### **Background**

ASN drew the attention of the group to the issue of medical diagnosis radiation exposures, which remain by far the largest man induced source of exposure to the population. The use of such medical tools is constantly growing as they provide effective means for diagnosing diseases, defining therapeutic strategies and following up treatments. Interventional radiology also constitutes a growing field since it provides minimally invasive ways of diagnosis as well as therapy under image guidance.

Although radiological imaging results in a net health benefit for the patients, ASN highlighted that due consideration should be given to limiting the medical doses delivered, as they may reach the threshold of the so called “low doses”, i.e. 50 mSv for children and 100 mSv for adults, above which statically significant increase of cancers has been established.

### **Discussion**

ASN presented its actions planned in France in the medical field as well as a proposed action plan for international organizations and radiation protection authorities, which the group found comprehensive and ambitious.

The discussion of the action plans led the group to the following conclusions:

- The need for better consistency in the regulatory approach for radiation protection between the nuclear safety domain and the medical domain (taking account of the great number of patients concerned, the radiation protection measures in the medical domain are generally considered too weak);
- The need for better consideration of the fundamental principles of “justification of activities” and “optimization of the protection” (principles 4 and 6 of the IAEA Safety Fundamentals publication) in the medical field;
- The imperious need for special consideration when it comes to children;
- The substitution by alternative medical imaging techniques such as MRI, where appropriate;
- The optimization of CT and digital imaging equipments, requesting the industry to lower the delivered doses, and encouraging experience feedback on protection optimization practices;
- The implementation of more robust and specific training programmes for all relevant medical professionals, fostering a better “radiation protection and safety culture” among the professionals, who are sometimes not aware of the extent of the risks;
- The reinforcement of international sharing of experience and concerted actions for radiological medical practices;
- The development of “peer review” programmes for medical practices (not only for the regulatory body but also for the practitioners), possibly under the joint auspices of the IAEA and the WHO (however the group recognized the complexity of developing such services since there may be thousands of radiologists within a country);
- The need for better coordination with other relevant authorities, such as those regulating the design and manufacture of devices (AFSSAPS in France), taking into account that these manufacturers are often multinational companies (thus enhancing the need for internationally concerted approaches);
- The reconsideration of the concept of “medical secrecy” so as to facilitate and improve the effectiveness of the inspectors’ work (in France some dosimetry-related information is

protected by medical secrecy, and inspectors cannot access it whereas it is established that the work of the inspectors is beneficial to the patients).

## 5. EMERGENCY PREPAREDNESS

### Considerations and Findings from IRRS 2006

ASN, together with its regional bodies (Divisions), is a central advisory body in emergency matters of radiological relevance. ASN collaborates closely with the IRSN in this area and directs its advice primarily to the ministerial level and to the Prefect(s) of the affected regions. Actions prompted by the emergency situations are taken by the operators for the on-site actions, and by the Prefect(s) of the affected region(s) in the case of the off-site actions.

Post-accident planning has had a lower priority in the past but is currently being subjected to upgrading, and is also recently being included as an essential element in emergency drills.

ASN has an emergency centre at the premises of its Paris office. It has the necessary facilities for communication with other organizations involved in the emergency network, for receiving vital information from operators as well as from IRSN, and for external communications. It is equipped to be able provide sustained function, including in situations where the outside infrastructure is under duress.

The regional offices (Divisions) play a vital and direct role in emergency events, and will send representatives to the Prefect and operator to provide technical support and to check information.

### Recommendations and Suggestions from IRRS 2006 Report

#### **RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION**

S45 **Suggestion:** ASN should continue its work towards an upgrading of post-accident planning, taking into account the specific local and national conditions, that can couple with the off-site emergency plans that are already available for a large number of sites.

### Changes since the IRRS 2006 Mission

Due to the upgrading process already mentioned in 2006 post accident planning reached higher priority in emergency preparedness. A working group (CODIRPA) is compiling a program that considers a transition and a post accident phase, following the emergency phase of the accident. Hereby it considers international experience feedback from incidents where a post accident phase has taken place. Due to the remaining radiological situation advisory is given for dealing with population and use of water, agricultural products, animals, waste, etc. depending on specific local and national conditions. Post accident phases are already included in emergency exercises starting mid-2008 in order to test the already existing recommendations from the CODIRPA results.

### Findings of the 2009 follow-up IRRS Mission

**Suggestion 45 is closed.**

## 5.2 RESOURCES AND ABILITIES

### Considerations and Findings from IRRS 2006

The number of ASN staff involved full-time in work on emergency preparedness is limited, but the number that is available to engage in work in an emergency situation is substantial. A large fraction of the staff carries pagers and the response time is very short.

A well-structured organigram has been developed for emergency organization. Key positions are reserved for individuals occupying certain positions in ASN, and are based on these individuals' functions in the every-day work of ASN. A weekly list is drawn up of staff members on duty, who should respond shortly after having been alerted. There is some lack of clarity in the manning and there could also be improvements in the record-keeping of training received by function specialists.

The organigram also identifies a spokesperson for ASN (a high-ranking staff member) who is responsible for all external communication matters, and in this area co-ordinates communication activities with the Prefect spokesperson and (when relevant) the operator's site and central spokespersons.

A particular issue is the dependence of ASN on IRSN in certain key areas, such as the provision of source term, dispersion modelling and dose forecasting, and the delivery of actual monitoring data in the case where a release occurs. In order to operate efficiently, this requires very rapid communication between ASN and IRSN to avoid delays in recommendations to the Prefect.

**Recommendations and Suggestions from IRRS 2006 Report**

<b>RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION</b>	
S47	<b>Suggestion:</b> ASN should seek to facilitate and accelerate, to the extent possible, communication with the IRSN to reduce the risk that relevant information for ASN's capacity to provide advice to the prefect is delayed.

**Changes since the IRRS 2006 Mission**

Regarding the aspect of delayed communication between ASN and IRSN it is said that the information exchange between their emergency centres has been formalized. Regular meetings are held between ASN and IRSN to share the experience feedback on the exercises. ASN/IRSN information form has been revised. In case of emergency ASN and IRSN set up their own crisis centers but connect them with a modern information exchange infrastructure up to the possibility of performing video conferences. During the 2009 follow-up mission no further hints are seen to a delayed information exchange between ASN and IRSN under emergency conditions. ASN has implemented Suggestion S47

**Findings of the 2009 follow-up IRRS Mission**

**Suggestion 47 is closed.**

**5.3 DECISION-MAKING IN EMERGENCY SITUATIONS**

**Considerations and Findings from IRRS 2006**

The emergency preparedness arrangements from organizational and other perspectives are complex and involve many players at the ministerial level, national authorities (ASN with IRSN), and regional (Prefects) and operational (individual plants where an emergency situation occurs) levels. However, there is clear allocation of responsibility for notification and decision-making. The role of ASN is an adviser to the government and competent (regional) authorities. Also, well-defined interfaces exist between operators and authorities.

The relatively large number of players and wide net of communications can, however, pose a potential source of delays and loss of information, in particular in the early phases of the emergency situation. Streamlining the emergency organization and communication routes might bring benefits.

ASN is strongly dependent on expert assessments performed by the IRSN, which are not necessarily reassessed by ASN, but which are synthesized together with other information available to ASN before being used to issue recommendations to the Prefect.

**Recommendations and Suggestions from IRRS 2006 Report**

<b>RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION</b>	
S48	<b>Suggestion:</b> ASN should review its own capability to assess the situation independently of the IRSN.

**Changes since the IRRS 2006 Mission**

In France a strict separation is intended between technical assessment (IRSN), and decision-making (ASN). ASN's role within this structure is to give advice to the prefect based on a technical assessment by IRSN. In this aspect ASN has no resources to have the formal capability to assess rough or field data in an emergency situation independently of IRSN, mainly because it would be considered as a duplication of public means. ASN has the capability to assess the situation on basis of the facts prepared and delivered by IRSN and other information available to ASN.

Findings of the 2009 follow-up IRRS Mission

Suggestion S48 is closed: has been incorporated into recommendation RF1 in chapter 3.

## 5.4 EXERCISES

### Considerations and Findings from IRRS 2006

ASN (supported by IRSN) carries out emergency preparedness drills 10-15 times per year with different plants and with different scopes and scenarios. With regards to NPPs, taking into account that there is only one principal type of reactor in France, this has led to the accumulation of a substantial technical knowledge base to understand and assess the large spectrum of safety threatening situations at the plant and to provide related advice and recommendations to the national and local level authorities.

However, the drills have extensively focused on the initial events of an emergency situation, typically to the emergency situation's first 6-8 hours. Much less has been planned, tested and exercised for post-accident situations.

The role of IRSN in assessing the safety situation at and the source term from the plant, as well as analysing and predicting the release (size, length and spread and transport), is vital, as is the operation of communications between IRSN and ASN during the emergency. Increased attention may have to be put on assessing the generic implications of specific scenarios for other installations, on-site or nation-wide.

### Recommendations and Suggestions from IRRS 2006 Report

#### RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

S46 **Suggestion:** ASN should introduce a systematic and traceable training programme for the staff allocated to key functions

### Changes since the IRRS 2006 Mission

The work on a training programme for staff allocated to key functions is well in progress. ASN has defined key function within the emergency organisation and established requirements for staff participating to emergency situations management. These key functions are direction, technical (three different due to kind of facility: NPPs, other BNIs, other nuclear activities), communication/international notification and logistics. ASN is preparing the implementation of an on-call arrangement that shall be active before summer 2009.

### Findings of the 2009 follow-up IRRS Mission

**Suggestion 46 is closed.**

## 6. INFRASTRUCTURE FOR RADIOACTIVE WASTE MANAGEMENT

### Considerations and Findings from IRRS 2006

The requirements for a national infrastructure for radioactive waste management are given in GS-R-1 § 6.7 to 6.13.

In 2006, ASN was coordinating the first National Plan for the Management of Radioactive Materials and Wastes through a working group. ASN had developed a draft plan with the participation of all stakeholders in the field that was published on ASN's website for public comments. The complete plan was due at the end of 2006. The leadership role of ASN was noted as a Good Practice in the 2006 IRRS Report.

Another point observed was that ASN was not directly responsible for the safety of remediation actions that are carried out under the control of the prefect and inspectors of ICPEs (Installations Classified on Environmental Protection Grounds). Nevertheless, ASN recommends to the local authorities that the radioactive waste be managed to comply with the ANDRA acceptance criteria for low level and very low level waste. ASN inspectors can assist the local inspectors to inspect the remediation of a polluted site. This situation was not well defined in regulations that led to the Suggestion S49 repeated below.

### Recommendations and Suggestions from IRRS 2006 Report

#### RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION

S49 **Suggestion:** ASN should continue its efforts to coordinate with the Ministry of the Environment to establish a common regulatory regime for the remediation of areas contaminated with radioactive materials including the safety of remediation actions that are carried out under the control of the prefect and inspectors of ICPEs (Installations Classified on Environmental Protection Grounds). ASN should also be involved in changes related to control of this kind of remediation, in cooperation with DPPR at the Ministry of the Environment.

### Changes since the IRRS 2006 Mission

**Suggestion 49 – remediation:** ASN has taken a number of actions to establish a common regulatory approach to contaminated areas and remediation with the Ministry responsible for protection of the environment. This includes the coordinated development of the National Plan for the Management of Radioactive Material and Waste (PNGMDR) as well as development of a common approach to contaminated areas. The two organizations have established a working group to allow IRSN, ANDRA, other waste facility operators and non-governmental organizations to contribute to the development of the next three-year National Plan.

The coordinated approach goes beyond the treatment of radioactive waste to assuring that a similar approach is used for both radioactive and non-radioactive materials. The two organizations have also jointly published a regulatory guide, along with the Ministry of Health, on radioactive waste and contaminated sites. This provides a reference framework for the remediation action carried out under the control of the prefect and completes the actions in the suggestion S49. Furthermore, they have jointly requested IRSN to develop the associated technical guidance.

### *Foreign waste*

Article 8 of the 2006 Programme Act stipulates, while making reference to the Environmental Code, *inter alia* that:

“The disposal in France of radioactive wastes from abroad and that of radioactive wastes resulting from the treatment of spent fuels and of radioactive wastes from abroad is forbidden”;

and,

“Spent fuels or radioactive wastes cannot be introduced into the national territory, save for treatment, research purposes or transfer between foreign States.

Their introduction for treatment can be authorised only as a part of intergovernmental agreements and provided the radioactive wastes resulting after treatment of these substances are not stored in France beyond a date set by said agreements.....”

In effect, disposal of foreign waste in France was prohibited also before the 2006 Planning Act. Cases where foreign waste is treated in France are rare. An application to carry out such activities will have to be submitted to the Ministry of Energy, which may subsequently approve or decline the application, taking the advice of ASN into account. The authorisation will also establish the conditions for return of the waste, including the procedures for establishing the ‘equality’ of waste returned relative to waste received.

### *Deep geological disposal*

The plans in France for siting and building a deep geological repository are advancing. The 2006 Programme Act declares such a facility being a BNI and further stipulates:

- that the application for authorisation has to be preceded by studies in an underground laboratory in the geological formation of concern;
- that the filing of the authorisation is preceded by a public debate;
- that the opinions of the territorial authorities are collected;
- that the application is subject to review by the National Assembly and the Senate; and,
- that the reversibility conditions are to be decided in an Act *and* that no authorisation can be given unless there is a guarantee for reversibility according to that act *and* that a subsequent act can authorise closure only after a minimum time of 100 years of reversibility.

It can be observed that the provisions on reversibility are relatively far-ranging but that there still remains some uncertainty as to what the term reversibility in reality means. Internationally, the distinction is often made between *reversibility* (the reversal of a process or a decision), *retrievability* (the retrieval of whole waste packages) and *recoverability* (the recovery of material, e.g. fissile material, from the waste package). ANDRA is currently working on a ‘scale of reversibility’. The ultimate meaning of reversibility will eventually be defined in the act governing reversibility. However, a more precise definition may be desirable, or actually needed, prior to this act for the consultation process and for effective communication with the public.

Since the 2006 mission, ASN has also revised its guidance on disposal in deep geological repositories<sup>11</sup>. The guidance describes the repository’s post-closure safety functions as:

- inhibition of the circulation of water in the disposal facility;
- containment of radioactivity; and,
- isolation of waste from humankind and from the biosphere so that the safety of the disposal facility is not significantly affected by climatic erosion or ordinary human activities.

The safety functions leads to a number of site selection criteria or factors, including:

- stability
- hydrogeology;

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<sup>11</sup>Safety guide on the permanent disposal of radioactive waste in deep geological disposal, ASN, 12 February 2008.

- respect of a minimum depth; and,
- no sterilisation of extractable underground resources (by which is meant that localisation in an area where there are underground resources should be avoided)

A further guide has been developed for site selection for low specific activity waste<sup>12</sup>, which is relevant to *intermediate-depth repositories*.

***Findings from the 2009 Follow-up IRRS Mission***

**Suggestion 49 is closed.** ASN has even gone beyond what can be reasonably expected, which forms a basis for identification of a Good Practice, as follows:

Further findings from the 2009 Follow-up Mission in the waste management area can be found in Sections 4.1.7, 4.2.5, 4.3.6 and 4.4.5 of this report.

**RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION**

(1) **BASIS:** GS-R-1; § 2.6 (13) states *“The regulatory body shall have the authority: ... to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, Safety, and transport of dangerous goods”*

GF9 **Good Practice:** ASN has established a formal relationship with the Ministry responsible for the environment allowing the development of a national approach to the treatment of contaminated sites regardless of who has the regulatory responsibility for the sites.

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<sup>12</sup>General safety guidelines for site selection for the storage of long lived low specific activity waste.

## 7 MANAGEMENT SYSTEM FOR THE REGULATORY BODY

### **Considerations and Findings from IRRS 2006**

Many key elements of ASN MS have been developed and implemented individually in ASN throughout its years of functioning. However, the development of a more integrated, organized and formalized MS was only shroty started before the 2006 mission and at the time of that review, MS was in its early phase.

Areas of security, physical protection and nuclear material accounting and control, which often are an integral part of the MS (GS-R-3, §2.1), did not fall under the responsibility of ASN and were therefore excluded from the MS review and follow-up review scopes.

The 2006 review covered three main dimensions of ASN MS:

- ASN's in-house management system, i.e. the management system applied at ASN,
- ASN's MS oversight of licensees' MS (e.g. safety culture),
- ASN's MS interface with and oversight of its TSO (IRSN) and its, as well as licensees', contractors and sub-contractors. This dimension considers how ASN ensures that the TSO, the licensee and the supply chain have an effective MS (including such aspects as safety culture); monitors the system and its performance (ensuring open channels to know what's going on in the operating organizations); and takes actions as needed.

During the 2006 mission, ASN was reorganized and a new five member Commission established. From a MS viewpoint, this represented two challenges to ASN - namely, the successful organizational change and the introduction and implementation of a cultural change.

Regarding the well developed elements of ASN management system, the main findings of the 2006 mission included the following:

- ASN's core processes,
- The new ASN strategy, goals and objectives, as described in a coherent manner in the published "Plan Strategique 2005 - 2007",
- The annual planning system,
- Clearly defined values, and
- The decision making process.

Less developed elements of ASN management system were found to include:

- Policy and documented (and demonstrated) senior management commitment to establish, implement, assess and improve the MS,
- Developing and documenting regulations,
- Integrating the elements of the MS of the regional offices into ASN MS,
- Human capital development: About 50% of the staff are civil servants resulting in a high staff turnover in comparison with regulatory bodies in many other countries, and
- Documenting and formalizing development and management of processes.

### **Recommendations and Suggestions from IRRS 2006 Report**

<b>RECOMMENDATIONS, SUGGESTIONS FROM THE 2006 IRRS MISSION</b>	
R33	<b>Recommendation:</b> In light of ASN reorganization and management responsibility, the new Commission and ASN senior management should establish and document a policy and demonstrate commitment to establish, implement, assess and improve ASN's management system.
R34	<b>Recommendation:</b> The development of ASN MS should be continued. As one of the next steps, a master plan with major milestones, time schedules and resource allocations should be prepared and implemented to guide the systematic development of its MS. The plan should address, inter alia, issues discussed above and the three main dimensions of the management system, <ul style="list-style-type: none"> <li>a. ASN's management system applied in-house,</li> <li>b. ASN's oversight of licensees' management systems, and</li> <li>c. ASN's oversight of TSO's and contractors' management systems.</li> </ul>
R35	<b>Recommendation:</b> In light of high staff turn over, including at management positions, regulatory needs related to the potential future developments in the use of nuclear energy, and competence as one of its core values, <ul style="list-style-type: none"> <li>- ASN should reconsider its human resource strategy in order to ensure ASN's long term competence and the effectiveness and efficiency of the competence building efforts;</li> <li>- ASN should ensure that the individual competence requirements (qualifications, education, experience) for each position in the organization are considered in a graded manner (relevance to safety), and that requirements are documented and followed.</li> </ul>
S50	<b>Suggestion:</b> In light of ASN's efforts to ensure greater consistency with IAEA safety standards, the requirements of GS-R-3, e.g. those related to safety culture, should be formalized, applied and enforced by ASN.

### **Changes since the IRRS 2006 Mission**

Since the 2006 IRRS mission, ASN has intensively developed and formalized its management system (MS) to address the recommendations and suggestions the IRRS team made. In general, progress made is very good. Many principal elements are completed and they create basis on which the development of the management system was ongoing at the time of the follow-up mission.

In the following, the changed with respect to the recommendations and suggestion given are discussed:

**Recommendation 33:** In light of ASN reorganization and management responsibility, the new Commission and ASN senior management should establish and document a policy and demonstrate commitment to establish, implement, assess and improve ASN's management system.

The ASN Commission issued "Rules of procedure" (binding working order and terms of reference stipulated in the legislation), which requires ASN Director General to prepare and coordinate a continuous quality management and improvement system.

Accordingly, ASN DG issued a quality policy 10.10.2007, which addresses and includes management commitment and requirements on policy level for the management system.

It is also noted that ASN Strategic Plan for 2007-2009 endorsed the importance of the MS. A particular chapter "Develop a common management culture" is devoted to MS emphasizing the main principles and management commitment in this direction.

**Recommendation 34:** The development of ASN MS should be continued. As one of the next steps, a master plan with major milestones, time schedules and resource allocations should be prepared and implemented to guide the systematic development of its MS. The plan should address, inter alia, issues discussed above and the three main dimensions of the management system,

- *ASN's management system applied in-house,*
- *ASN's oversight of licensees' management systems, and*
- *ASN's oversight of TSO's and contractors' management systems.*

#### **ASN's management system applied in-house,**

Since the 2006 IRRS mission, the development of ASN MS has continued intensively. Staff participation and creation of an in-house network of quality management officers, who currently meet on regular basis, was organized. In 2007, an external consultant was used to support the MS development efforts, in particular to identify and assess gaps between ASN's MS and ISO 9001-2000 standards.

In October 2007, a master plan with major milestones, time schedules and resource allocations was prepared and approved by ASN management to guide the systematic development of its quality management system (QMS). This plan, which is currently in implementation, has the following main seven areas of work:

1. identifying and improving of core and sub-processes (takes into account GS-R-1),
2. document control and management,
3. stakeholder relationships,
4. hearing processes,
5. formalization and implementation of the QMS on national level,
6. formalization and implementation of the QMS on regional level, and
7. feedback and continuous improvement.

Other important actions ASN has taken to support the development of the MS include

- establishment of a new organizational unit "Management and Expertise Office" reporting on regular basis on MS issues to the DG
- almost full time position to manage the development of the MS and a in-house network of representatives

It was positively noted, that ASN's DG has taken an active role in the development of the MS.

A challenge ASN is addressing in senior management level (and documented in the Strategic Plan 2007-2009) is the development of a common management culture for the headquarter and regional offices.

#### **ASN's oversight of licensees' management systems**

ASN's oversight of licensees' management systems is included in inspection activities, in particular in the areas of quality assurance and safety management. However, ASN has recognize the need to revisit and develop the MS oversight issue. This includes such planned and ongoing activities as:

- revision of regulations,
- feedback from operational experience, periodic safety reviews etc. to regulatory programs and activities,

- human factors: ASN has currently two dedicated professionals on organizational matters, and
- training in MS and QA.

Requirements to use self-assessments are under consideration.

### **ASN's oversight of TSO's and contractors' management systems**

As discussed in the 2006 Mission report (§ 3.3 and Annex IV) elsewhere in this report, ASN is very strongly supported by IRSN, which is the main TSO for ASN. In particular, this strong support is provided to one of the main regulatory functions of ASN, namely review and assessment. Therefore, it is uttermost important for ASN to be able to independently ensure that IRSN's review and assessment work is carried out in accordance with ASN's MS and QMS requirements.

IRSN is ISO 9001-2000 certified, which provides overall formal assurance of the quality system of IRSN to ASN. However, taking into account the central role of review and assessment carried out by the IRSN for ASN, it was surprising to learn that ASN has not audited these functions of IRSN against ASN MS requirements.

*R35: In light of high staff turn over, including at management positions, regulatory needs related to the potential future developments in the use of nuclear energy, and competence as one of its core values,*

- *ASN should reconsider its human resource strategy in order to ensure ASN's long term competence and the effectiveness and efficiency of the competence building efforts;*
- *ASN should ensure that the individual competence requirements (qualifications, education, experience) for each position in the organization are considered in a graded manner (relevance to safety), and that requirements are documented and followed.*

ASN is addressing this recommendation. Competence is one of values of ASN, which devotes a lot of efforts to ensure a high level of competence of its staff. ASN has reshuffled few of its departments; one of these objectives was to clarify the human resource management. From now on, office of administration is responsible for all Human Resource issues, including competence and training. ASN has hired a human resource expert and is redefining its competence policy and training programs. These programs cover both technical and managerial needs.

Identifying key competences to insure the ASN missions is an action of the 2009 ASN strategic plan. ASN has already established requirements for its staff participating in emergency preparedness.

**Suggestion 50:** In light of ASN's efforts to ensure greater consistency with IAEA safety standards, the requirements of GS-R-3, e.g. those related to safety culture, should be formalized, applied and enforced by ASN.

Based on its self-assessment, ASN is developing its MS to greater consistency with GS-R-3. In light of requirements of the GS-R-3, main existing non-compliances have been identified. These main issues are document formalization and control, stakeholder hearing formalism and formalization of safety culture. In most GS-R-3 areas, the correspondence exists today.

Regarding formalizing and enforcing of safety culture, ASN has somewhat pursued the issue but has been waiting for more IAEA and other international guidance and considerations. Implementation of safety culture for regulatory functions and activities is in general an evolving issue.

Based on ASN decision to carry out periodic self-assessments, a new one against GS-R-3 is planned to take place.

### **Findings from the 2009 IRRS Mission**

With respect to R33, R34 and and S50 ASN's activities are fully satisfactory **CLOSED**.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

- (1) **BASIS:** GS-R-3: §6.1 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 §6.3 states that *“Independent assessments shall be conducted regularly on behalf of senior management:*
  - *To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives;*
  - *To determine the adequacy of work performance and leadership;*
  - *To evaluate the organization’s safety culture;*
  - *To monitor product quality;*
  - *To identify opportunities for improvement.”*
- (3) **BASIS:** GS-R-3 §6.6 states that *“Senior management shall evaluate the results of the independent assessments, shall take any necessary actions, and shall record and communicate their decisions and the reasons for them.”*

RF3 **Recommendation:** ASN should audit IRSN’s review and assessment functions against ASN’s MS requirements.

## 8. CODE OF CONDUCT ON SAFETY AND SECURITY OF SOURCES

The Code of Conduct on the Safety and Security of Radioactive Sources is directed toward the activities of States; however, many of the Basic Principles of the Code concern the Authority and activities of the regulatory body. This review was based on interviews and documentation supplied by ASN and it was from their perspective that the implementation of the Code was considered. Many of the detailed principles of the Code of Conduct are also the subject to the requirements in GS-R-1, GS-R-3 and the BSS, and they have been addressed in other sections of the 2006 IRRS report and in this report. With these considerations in mind, this review of the implementation of the Code was focused on several main areas that are either unique to the Code or are emphasized within its General Principles:

- Regulatory Authority for the Security of radioactive sources.
- National register of radioactive sources
- Radioactive sources export – import
- Management of disused radioactive sources.
- Efforts to gain and regain control over orphan sources domestically.
- Scrap Metal Facilities

In a letter to the IAEA's Director General dated 7 January 2004, France's representative to the IAEA indicated that France is working toward the principles of the Code in accordance with resolution GC(47)/RES/7.

### **Regulatory authority for the security of radioactive sources**

Although ASN was established in 2006 as the independent regulatory body for the safety of nuclear installations and radioactive sources, it was not specifically charged with the regulation of the security of radioactive sources. In particular, the security-related principles of the IAEA *Code of Conduct for the Safety and Security of Radioactive Sources* (CoC) were not formally addressed domestically through relevant laws and codes, making it unclear if certain requirements for enhanced security could be legally imposed and enforced. This discrepancy was realized and in June 2008 ASN was instructed by the Prime Minister's Chief of Staff to propose a plan to establish regulatory control of the security of radioactive sources that addressed necessary organizational changes, regulatory changes, and staff and budgetary requirements.

ASN completed and submitted the proposal to the Prime Minister in November 2008. The proposal included the establishment of ASN as the regulatory body for security, specifically stating that the Directorate of Industrial Activities and Transport (DIT), which currently regulates the safety of radioactive sources, would handle this function. The proposal was completed in consultation with all relevant government bodies, including high level bodies responsible for national security (SGDN and HFDS). The proposal specifies an action plan under which the Government would retain responsibility for defining the threat levels under paragraph 16 of the CoC, but ASN/DIT would undertake all other relevant technical and regulatory work, including requiring trustworthiness checks of people as required by paragraph 20(e) (viii) of the CoC and proposing changes to all relevant laws and domestic regulatory codes, in particular the Health Code and Labour Code. The action plan also specified a list of tasks that ASN/DIT would undertake to implement the CoC once its proposal is approved. As of the date of this report, ASN is awaiting approval from the Prime Minister's office for its proposal.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

- (1) **BASIS:** General Principles 18, 19, 20, 21 and 22 of the Code of Conduct for the Safety and Security of Radioactive Sources state that, “*inter alia, legislation and/or regulations should provide for the establishment of a regulatory body that has the authority to establish regulations and issue guidance relating to the safety and security of radioactive sources.*”
- RF4 **Recommendation:** ASN should implement its proposal for the regulation of the security of radioactive sources expeditiously.

### National register of radioactive sources

A national system of registration of radioactive sources has been in existence since the 1950s. The Système d’information et de gestion de l’inventaire des sources de rayonnements ionisants (SIGIS) is an electronic database (the Register) that has been maintained by various organizations at Fontenay-aux-Roses for about the past 20 years. Until 2002, one organization (CIREA) managed the operation of the Register, and the registration of sources and licensing of persons. In 2002, these activities were split between the IRSN and ASN with the former retaining the operation of the Register and the registration of sources and the latter handling the regulatory processes of licensing, inspections and enforcement. While ASN’s Directorate of Industrial Activities and Transport (DIT) retained the regulatory functions for some 200 suppliers of radioactive sources, these functions for all other authorized persons were further devolved to ASN’s 11 regional Divisions.

The new arrangement has been found to be effective for the regulatory function of ASN/DIT as the DIT can access the information in the Register real-time through a direct physical connection to IRSN. Although the IRSN maintains the Register, the information comprises both details of licensees as well as sources. However, the 11 regional Divisions of ASN, who among them regulate some 7,200 licences and 30,000 sources (90% of the regulatory activity of radioactive sources) have no real-time electronic access to the Register. Any check against the Register by a Division needs to be done manually by requesting for a spreadsheet extract from the Register of relevant information regarding a potential or existing licensee. If this is not done for some reason, that Division may potentially issue a licence to someone who has been denied a licence in another Division.

To overcome the problem of the regional Divisions not having real time electronic access to the Register, the IRSN and the DIT have developed and tested a web-based intranet system of sharing information from the Register among IRSN, ASN and the 11 Divisions and the system is ready to be rolled out provided funds are allocated for the proposed web-based Register. However, it was pointed out that the DIT is facing the prospect of losing real-time access to the Register if an upgrade to its software is not installed due to funding constraints. ASN feels that such a situation would be unsatisfactory as it would result in the existence of two parallel databases – one for licensing of persons and another for registration of sources with information being exchanged manually between the IRSN and DIT, which would be cumbersome to use and potentially introduce errors.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

- (1) **BASIS:** CoC General Principle 11. states that “*Every State should establish a national register of radioactive sources. This register should, as a minimum, include Category 1 and 2 radioactive sources as described in Annex 1 to [the CoC]. The information contained in that register should be appropriately protected. For the purpose of introducing efficiency in the exchange of radioactive source information between States, States should endeavour to harmonize the formats of their registers.*”

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

- (2) **BASIS:** GSR1 section 3.38 states that “*In order to discharge its main responsibilities as outlined in paragraph 3.2 the regulatory body shall ensure that appropriate records relating to the safety of facilities and activities are retained and retrievable.*”
- SF5 **Suggestion:** ASN should have unhindered and continuing access to and control over records regarding the registration of radioactive sources and licensing of authorized persons, and ASN should consider owning and/or operating the Register (SIGIS) in the future. Furthermore, ASN, including its 11 Regional Divisions, should have real-time electronic access to the Register (SIGIS).
- GF10 **Good Practice:** France has operated a comprehensive register of sources for many years. The Register includes sources of all IAEA source categories which exceeds the categories specified in General Principle 11.

### Import and export of radioactive sources

Under Article R1333-49 of the Health Code, any import or export of radioactive sources from or to any country other than EC states must be registered in advance with the IRSN. The registration, coupled with consent by ASN is required as part of the Customs documentation for the import and export of any radioactive source. The consent process by ASN follows the principles in paragraphs 23 to 28 of the CoC as well as the *Guidance on the Import and Export of Radioactive Sources*. The requirement of ASN for the import or export of any radioactive source is prescribed as conditions of licence issued to a person to deal with a radioactive source. ASN is currently in the process of drafting a Decision from the ASN Commission to formalize these requirements and elaborate Article R1333-49. When completed the Decision from the ASN Commission will have the legal standing of a Ministerial Order. Also, while ASN has provided assurances that it is complying with the requirements of the *Guidance on the Import and Export of Radioactive Sources*, including nominating contact points, the Government has not yet made a commitment to the IAEA to implement the *Guidance on the Import and Export of Radioactive Sources* in accordance with General Conference Resolution GC(48)/RES/10.D.

A significant issue highlighted by ASN is the need to ensure that the requirements for the security of radioactive sources are harmonized with the requirements and processes of the French Customs Service. Radioactive sources and equipment and devices comprising radioactive sources are unique and pose dangers that are different from normal non-hazardous goods handled by Customs. There is a need for Customs to ensure that its processes to deal with packages containing radioactive sources take into account all laws and codes for the safety and security of radioactive sources. ASN has indicated that it has made several unsuccessful attempts to engage the Customs regarding these matters.

A related issue is the Customs monitoring of entry and exit points. ASN is concerned that there is now no portal monitor at any border entry/exit point to detect radioactive sources. ASN has brought this issue to the attention of Customs and all relevant government bodies, including high level national security bodies, the police and intelligence services.

Another related issue is the *transit or transshipment* of radioactive sources through French territory. General Principle 29 of the CoC requires particular attention to be paid to maintaining ‘continuity of control’ during the transport of a radioactive source through a transit or transshipment State. France shares common borders with six States. However, there is now no memorandum of understanding or bi-lateral agreement to ensure that ASN and its counterparts in these States have agreed common procedures on maintaining ‘continuity of control’ of radioactive sources during transit or transshipment. A European Council Regulation/EURATOM 1493/93 on Shipments of Radioactive Substances among Member States does address this issue, but its requirements are not in line with the CoC and there is no requirement in the EC Regulation for ‘continuity of control’. Instead the EC Regulation requires one Member State to provide information to another Member State on any

shipment but the information need not be provided before a shipment and could be provided after the shipment is completed. ASN has engaged the EC on the issue and is working towards harmonizing the EC Regulation with the CoC.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

- (1) **BASIS:** CoC General Principle 13 (b) states that “*Every State should [inter alia] encourage bodies and persons likely to encounter orphan sources during the course of their operations (such as scrap metal recyclers and customs posts) to implement appropriate monitoring programmes to detect such sources.*”
- (2) **BASIS:** CoC General Principle 20 (j) states that “*Every State should ensure that the regulatory body established by its legislation has the authority to [inter alia] monitor, or request other authorized bodies to monitor, at appropriate checkpoints for the purpose of detecting orphan sources.*”

SF6 **Suggestion:** ASN should make a formal request to Customs to use appropriate monitoring equipment at entry/exit checkpoints for the purpose of for example detecting orphan sources.

### Management of disused sources

A robust system that addresses the problem of disused sources has been developed in France; the two main components of this system are the requirements that authorized persons transfer disused sources to an authorized recipient, and a regime that places the primary responsibility for the disposal of all sources including disused sources on source suppliers.

Article R.1333-52 of the Public Health Code states: “Suppliers of sealed radioactive sources and products or devices containing them are obliged to recover, with no conditions and upon request, any sealed source that it has distributed, in particular when this sources is out of date or if its holder no longer has a use for it.” Furthermore, information about the plans of source suppliers for the disposal of sealed sources are required to be included in their requests for authorization. Additional information about the return of sources to suppliers has been provided in Section 4.4.5 of the 2006 IRRS Report.

Financial warranties concerning the end of life management of sealed sources, the establishment of which is the responsibility of source suppliers, are required by the Public Health Code, Chapter III, Article L1333-7 (See Section 1 Recommendation 2). The transfer of sources is tightly controlled by ASN and records are maintained within the SIGIS of all sources that have been distributed by suppliers. On an annual basis, ASN audits their records to ensure that financial warranties have been secured for all sources that have been distributed.

The Public Health Code, Chapter III, Article R.1333-52 states: “Any person using sealed radioactive sources is obliged to have sources that are out of date or which are no longer to be used collected by the supplier.” The status of the use of sealed radioactive sources is assessed by ASN during inspections, when licenses are amended or renewed, and when authorizations for the use of specific sources are renewed or terminated. The authorized person is obligated to notify ASN in the case of major changes to their operations such as bankruptcies. In an attempt to ensure that disused sources that may be part of a bankruptcy settlement are handled appropriately, ASN has written several times to the association of liquidators informing them of the possible presence of orphan sources.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION

- (1) **BASIS:** CoC General Principle 15. states that *Every State should, in implementing this Code, emphasize to designers, manufacturers (both manufacturers of radioactive sources and manufacturers of devices in which radioactive sources are incorporated), suppliers and users and those managing disused sources their responsibilities for the safety and security of radioactive sources.*
  - (2) **BASIS:** CoC General Principle 20 (e) (vii). states that *Every State should ensure that the regulatory body established by its legislation has the authority to [inter alia] attach clear and unambiguous conditions to the authorizations issued by it, including conditions relating to [inter alia] the safe and secure management of disused sources, including, where applicable, agreements regarding the return of disused sources to a supplier;*
  - (3) **BASIS:** CoC General Principle 22 (b). states that *Every State should ensure that its regulatory body [inter alia] ensures that arrangements are made for the safe management and secure protection of radioactive sources, including financial provisions where appropriate, once they have become disused.*
- GF11 **Good Practice:** Strong measures have been established for ensuring the effective management of disused sources including provisions for the return of sources to their suppliers and financial warranties that address the possible default of these source suppliers.

### Efforts to gain and regain control over orphan sources domestically

As stated in the 2006 IRRS report, ASN, together with its regional bodies (DSNRs), participates in emergency situations such as orphan source events as an advisory body. As required by the Public Health Code, Chapter III, Article R. 1333-93, prefects are principally charged with handling orphan sources that are discovered within their departement. This article also states that ASN and ANDRA will provide advice in determining which measures should be taken and that the measures taken shall be compatible with the national radioactive materials and waste management plan. When orphan sources are discovered the prefect will attempt to identify the final holder or the supplier and to make arrangements for its transfer to an authorized recipient. Activities related to the handling of the orphan source and remediating contamination are implemented by private companies or the IRSN at the behest of the prefect. If the final holder or supplier cannot be identified, ANDRA is charged with arranging for the disposition of the source. In 2006, specific funding was established for the disposition of orphan sources.

The Public Health Code, Chapter III, Article R. 1333 requires that, inter alia, the loss or theft of radioactive sources or product or devices containing them must be immediately reported to the prefect of the department in which the site is located. The prefect is then required to notify ASN or the Delegate for Nuclear Safety and and Radiation Protection for defence-related nuclear activities and installations and IRSN.

During regular inspections, ASN inspectors verify that all sources assigned to a facility in the SIGIS database are physically present. In cases where the expected sources are not physically present, a graded approach by ASN is implemented to address the discrepancy. ASN staff members indicated that problems are sometimes found with the register entries for researchers and that ASN often suspends their authorizations pending resolution of the issue. In most cases, a simple explanation such as an unauthorized transfer to a fellow researcher or a misplaced source is the cause of the missing source.

ANDRA has conducted several campaigns in recent years aimed at regaining control over orphan sources that are known to individuals who possess them. The last of these campaigns was conducted in 2004. This campaign alerted the public to the possible presence of orphan sources and provided instructions for bringing sources to collection points or notifying the prefect of the departement of their presence. Typical sources that were collected were lightning rods containing radioactive

material and Ra-226 sources. ASN staff members indicated that they are occasionally contacted regarding Ra-226 sources that have been used in the past in medical procedures. They also indicated there have been some incidents in which radioactive luminescent paint has been dropped off anonymously at police stations. In all of these instances, the sources were dispositioned in accordance with regulatory requirements. Future radioactive source collection campaigns are planned for the collection of smoke detectors containing radioactive material.

### **Scrap Metal Recycling**

Regulations that apply to scrap metal collection facilities are issued by the Department of the Environment where they are treated as Installations Classified on Environmental Protection Grounds. These requirements specify some type of radiation monitoring for the presence of radioactive material in scrap metal. It appears that ASN staff members have little official contact with the Ministry of Environment regarding radiation monitoring of scrap metal; however, they did indicate that many of these facilities have portal monitors that monitor trucks containing scrap metal. ASN staff members also indicated that investigation levels for radiation that reflect radiation safety concerns have not been established.

As stated in Section (Import and export of radioactive sources), there is no radiation monitoring of shipments that are import to, or exported from, France that would detect the presence of radioactive material in cross-border shipments of scrap metal.

### **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES FROM THE 2009 IRRS MISSION**

- (1) **BASIS:** CoC General Principle 13 b. states that “Every State should [inter alia] encourage bodies and persons likely to encounter orphan sources during the course of their operations (such as scrap metal recyclers and customs posts) to implement appropriate monitoring programmes to detect such sources.”
- SF7 **Suggestion:** ASN should offer its support and technical expertise to the Ministry of the Environment regarding the development of appropriate monitoring programmes to detect orphan sources that may be present in scrap metal.

## APPENDIX I – LIST OF PARTICIPANTS

<b>INTERNATIONAL EXPERTS:</b>		
1. Len <b>CRESWELL</b>	Nuclear Installation Inspectorate (NII)	<a href="mailto:Len.Creswell@hse.gsi.gov.uk">Len.Creswell@hse.gsi.gov.uk</a>
2. Andrew Craig <b>MCEWAN</b>	New Zealand	<a href="mailto:acmcewan@clear.net.nz">acmcewan@clear.net.nz</a>
3. Tero <b>VARJORANTA</b>	Radiation and Nuclear Safety Authority (STUK)	<a href="mailto:Tero.Varjoranta@stuk.fi">Tero.Varjoranta@stuk.fi</a>
4. Javier <b>ZARZUELA</b>	Consejo de Seguridad Nuclear (CSN)	<a href="mailto:jzj@csn.es">jzj@csn.es</a>
5. Carl-Magnus <b>LARSSON</b>	Swedish Radiation Protection Authority	<a href="mailto:Carl-magnus.larsson@ssi.se">Carl-magnus.larsson@ssi.se</a>
6. Jean-Paul <b>SAMAIN</b>	Federal Agency for Nuclear Control (FANC)	<a href="mailto:Jean-Paul.Samain@wr-cs.be">Jean-Paul.Samain@wr-cs.be</a>
7. Peter <b>ELDER</b>	Canadian Nuclear Safety Commission (CNSC)	<a href="mailto:Peter.Elder@cnsccsn.gc.ca">Peter.Elder@cnsccsn.gc.ca</a>
8. Sandra <b>GABRIEL</b>	US Nuclear Regulatory Commission (USNRC)	<a href="mailto:sandra.gabriel@nrc.gov">sandra.gabriel@nrc.gov</a>
9. Bruce Alan <b>BOGER</b>	US Nuclear Regulatory Commission (USNRC)	<a href="mailto:Bruce.Boger@nrc.gov">Bruce.Boger@nrc.gov</a>
10. Bernd <b>LINSENMAIER</b>	Swiss Federal Nuclear Safety Inspectorate (ENSI)	<a href="mailto:Bernd.Linsenmaier@ensi.ch">Bernd.Linsenmaier@ensi.ch</a>
11. Selva <b>KUMAR</b>	Australian Radiation Protection Nuclear Safety Agency (ARPANSA)	<a href="mailto:Selva.Kumar@arpansa.gov.au">Selva.Kumar@arpansa.gov.au</a>
12. Kiyoharu <b>ABE</b>	Nuclear and Industrial Safety Agency (NISA)	<a href="mailto:abe-kiyoharu@meti.go.jp">abe-kiyoharu@meti.go.jp</a>
<b>IAEA STAFF MEMBERS</b>		
1. Gustavo <b>CARUSO</b>	Division of Nuclear Installation Safety	<a href="mailto:G.Caruso@iaea.org">G.Caruso@iaea.org</a>
2. Eric <b>REBER</b>	Division of Radiation Transport and Waste Safety	<a href="mailto:E.Reber@iaea.org">E.Reber@iaea.org</a>
3. Pierre <b>PERDIGUIER</b>	Division of Nuclear Installation Safety	<a href="mailto:P.Perdiguiier@iaea.org">P.Perdiguiier@iaea.org</a>
4. Marlene <b>KOBEIN</b>	Division of Nuclear Installation Safety	<a href="mailto:M.Kobein@iaea.org">M.Kobein@iaea.org</a>
<b>OFFICIAL ASN LIAISON OFFICER:</b>		
1. Jean-Rene <b>JUBIN</b>	Autorité de sûreté nucléaire (ASN)	<a href="mailto:Jean-Rene.JUBIN@asn.fr">Jean-Rene.JUBIN@asn.fr</a>

## APPENDIX II – MISSION PROGRAMME

Sunday 29<sup>th</sup> March 2009

### 13h15 .....LOGISTIC ISSUES

Attendees: IRRS Team and Liaison Officer (Mr Jubin)

- Liaison Officer meets IRRS Team at all seasons Paris Bercy Hotel in the lobby at 13h15
- Logistic and domestic arrangements (Mr Jubin)

### 14h00 .....Entrance meeting (room 1210)

Attendees: Mrs Comets and Mr Gouze (ASN Commissioners),  
Mr Niel (ASN DG), IRRS Team Members, ASN Counterparts, and Liaison Officer

### 14h00 – 14h45 .....INTRODUCTION

- Welcome (Mr Niel)
- Attendee introductions (All)
- Team opening remarks (Team Leader: Mr Creswell)
- ASN IRRS Context and ASN follow-up objectives (Mr Niel) (5')
- Contents of the ASN IRRS Follow-up mission (IAEA Coordinator: Mr Caruso) (10')
- Mission agenda (Mr Jubin) (10')

### 14h40 – 17h00 .....PRESENTATIONS

- ASN presentation (Mrs Comets) (10')
- Overview on action plan implementation, including presentation and discussion (15' max. per topic)
  - Management system (Mr Mochel)
  - Human resources (Mr Chaniel)
  - IRSN relationship (Mrs Baudoin)
  - Regulation on nuclear safety (Mr Gupta, Mr Mochel)
  - Sanction and enforcement (Mr Lachaume)
  - Experience feedback (Mr Lachaume)
  - Waste management (Mr Rieu)
  - Radiotherapy (Mr Krembel)
  - Research for regulatory purpose (Mrs Baudoin)

### 17h00 – 17h30 .....SELF-ASSESSMENT & ACTION PLAN

- Overview on ASN self-assessment against the Code of Conduct (Security of Radioactive Sources) (Mr Landier)
- Action plan presentation and discussion (Mr Landier, Experts)

### 17h30 – 18h00 .....CONCLUSION (Mr. Creswell and Mr. Niel)

### 18h00 .....Meeting adjourned

**Monday 30<sup>th</sup> March 2009**

**09h00 .....IRRS Opening meeting**

*Attendees: IRRS Team Members, ASN Commissioners, ASN Executive Board, ASN regional representatives, ASN Counterparts, Liaison Officer, Mr Lelièvre (ASN Paris division), Mr P Deschamps (IRSN) and Mr Billarand (IRSN)*

- Welcome and opening comments by Mr. Lacoste (ASN Chairman)
- Attendee introductions (All)
- Opening comments by Mr Creswell (Team Leader)
- Mission agenda overview by Mr Jubin

**09h30 .....INTERVIEWS**

**18h00 .....Daily IRRS Team meeting**

**Tuesday 31<sup>st</sup> March 2009**

**08:00 .....Mr Tredinnick and Mr Reber take ASN taxi at Bourgoin to FAR.**

**08h30 .....Policy discussions “nuclear medical issues”**

*Attendees: IRRS Experts, ASN Commissioners, ASN Executive Board Members, ASN regional representative*

**10h30 .....ASN Commission meetings**

*Observers: JP Samain, P Elder, L Creswell, G Caruso*

**10h30 .....Interviews (see excel matrix agenda)**

**12h30 .....Mr Lelièvre meets Mrs Gabriel and Mr McEwans at Bourgoin to radiotherapy inspection observation**

**14h00 .....Advisory committee meeting on radiation protection**

*Observers: P Elder...*

**18h00 .....Daily IRRS Team meeting (room 1207)**

**Wednesday 1<sup>st</sup> April 2009**

**08:00 .....Mr Tredinnick and Mr Reber take ASN taxi at Bourgoin to FAR.**

**08h30 .....Policy discussions “independence of Regulatory Body” (room 2250)**

*Attendees: IRRS Experts, ASN Commissioners, ASN Executive Board Members, , ASN regional representatives*

**10h30 .....Interviews (see excel matrix agenda)**

**18h00 .....Daily IRRS Team meeting (room 1207)**

**19h00 .....Social event : Diner at Hôtel Régina**

*Attendees: IRRS Team Members, ASN Commissioners, ASN Executive Board, ASN regional representatives, ASN Counterparts, Liaison Officer, Mr Lelièvre (ASN Paris division)*

**Thursday 2<sup>nd</sup> April 2009**

**08h30 .....Experts meeting – Report drafting (room 1207)**

**14h00 .....Bilateral discussion (Expert / Counterpart) discussions on draft**

*Attendees: IRRS Team Members, ASN Counterparts*

**17h00 .....Draft report handed over to ASN Commissioners, ASN Executive Board Members**

**Friday 3<sup>rd</sup> April 2009**

**08h30 .....ASN plenary discussion on draft report (room 1210)**

*Attendees: ASN Commissioners, ASN Executive Board, ASN Counterparts, Liaison Officer*

**10h30 .....ASN/IRRS Team plenary meeting (room 1210)**

*Attendees: IRRS Team Members, ASN Commissioners, ASN Executive Board, ASN Counterparts, Liaison Officer*

**12h00 PHOTO SESSION**

**14h00 .....Report Finalisation by Experts in Relation with Counterparts (room 1210)**

**16h00 .....Exit Meeting (room 1210)**

*Attendees: IRRS Team Members, ASN Commissioners, ASN Executive Board, ASN regional representatives, ASN Counterparts, Liaison Officer, Mr Lelièvre (ASN Paris division), Mr P Deschamps (IRSN) and Mr Billarand (IRSN)*

- Mr Creswell mission conclusion overviews
- Mr Lacoste closing comments

**16h30 .....Farewell Drink (room 1210)**



**APPENDIX III – RECOMMENDATIONS/SUGGESTIONS/GOOD PRACTICES FROM THE FOLLOW-UP IRRS MISSION**

	<b>AREAS</b>	<i>Rf: Recommendations, S: Suggestions, G: Good Practices</i>	<i>RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES ARISED FROM THE FOLLOW UP MISSION</i>
	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	<i>No Recommendations/Suggestions where made in this Chapter</i>	
<b>2.</b>	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	<b>GF1</b>	<b>Good Practice:</b> (from the Recommendation 5): ASN has created an organization specifically devoted to produce standards that involves ASN and IRSN experts, consults regulated industry, and a system to ensure consistency, completeness and state of the art of the standards produced.
<b>3.</b>	ORGANIZATION OF THE REGULATORY BODY	<b>GF2</b>	<b>Good Practice:</b> ASN takes significant part in harmonizing actions at the European level: European directive, and proactive and leading activities at the international level.
		<b>GF3</b>	<b>Good Practice:</b> ASN puts strong emphasis to avoid being isolated among relevant stakeholders establishing convention and protocols with local, national and international stakeholders.
		<b>GF4</b>	<b>Good Practice:</b> the ASN commissioners take into account long term consideration and regulatory positions in order to ensure long term safety in France and abroad.
		<b>GF5</b>	<b>Good Practice:</b> At the side of training we consider that the strong improvement of the training courses with modular composition of the courses and specific modules dedicated to specific area giving a comprehensive education to the personnel could be regarded as a good practice.]

		<b>RF1</b>	<b>Recommendation:</b> ASN should: <ul style="list-style-type: none"> <li>- Improve and facilitate the staff recruitment and the flexibility in order to obtain the necessary experienced staff on time and during the necessary period to carry out the regulatory activities</li> <li>- Exchange experienced staff mainly from IRSN and other organizations have be improved significantly.</li> </ul>
		<b>RF2</b>	<b>Recommendation:</b> ASN should: <ul style="list-style-type: none"> <li>- Work with IRSN and the government to allow ASN to have specific oversight of the IRSN budget for regulatory reviews and assessments; and</li> <li>- Continue to develop its core competence in all areas of review and assessment in order to define and oversee the technical support needed for regulatory purposes.</li> </ul>
		<b>GF6</b>	<b>Good Practice:</b> The development of a common strategy for international relations between ASN and IRSN is considered to be a good practice.
		<b>SF1</b>	<b>Suggestions:</b> Recognizing the above Good Practice, ASN should work with IRSN to extend this approach to develop common strategies in other areas such research, human resources and communication.
4.	ACTIVITIES OF THE REGULATORY BODY	<b>SF2</b>	<b>Suggestion:</b> In view of the critical role medical physicists have in ensuring accurate dose delivery in radiotherapy, newly graduated physicists should work in liaison with an experienced physicist.
		<b>GF7</b>	<b>Good practice:</b> The development of the ASN-SFRO severity scale as a tool to convey understanding of the significance of reported events and the development of the risk self-assessment guide for radiotherapy.
		<b>SF3</b>	<b>Suggestion:</b> ASN should consider adding an analysis of differences in annual doses from discharges from different nuclear installations, based on the input from IRSN, to the ASN Annual Report.
		<b>GF8</b>	<b>Good Practice:</b> The placement of radiotherapy practice inspection reports on the ASN website is a powerful enforcement tool.

		<b>SF4</b>	<b>Suggestion:</b> ASN, in collaboration with relevant ministries and other organisations concerned, should implement the technical guidance on remediation of polluted or contaminated sites that is currently being developed by IRSN, to assist regional authorities and ANDRA in remedial actions.
<b>5</b>	EMERGENCY PREPAREDNESS	<i>No Recommendations/Suggestions where made in this Chapter</i>	
<b>6</b>	INFRASTRUCTURE FOR RADIOACTIVE WASTE MANAGEMENT	<b>GF9</b>	<b>Good Practice:</b> ASN has established a formal relationship with the Ministry responsible for the environment allowing the development of a national approach to the treatment of contaminated sites regardless of who has the regulatory responsibility for the sites.
<b>7</b>	MANAGEMENT SYSTEM FOR THE REGULATORY BODY	<b>RF3</b>	<b>Recommendation:</b> ASN should audit IRSN's review and assessment functions against ASN's MS requirements.
<b>8</b>	CODE OF CONDUCT ON SAFETY AND SECURITY OF SOURCES	<b>RF4</b>	<b>Recommendation:</b> ASN should implement its proposal for the regulation of the security of radioactive sources expeditiously.
		<b>SF5</b>	<b>Suggestion:</b> ASN should have unhindered and continuing access to and control over records regarding the registration of radioactive sources and licensing of authorized persons, and ASN should consider owning and/or operating the Register (SIGIS) in the future. Furthermore, ASN, including its 11 Regional Divisions, should have real-time electronic access to the Register (SIGIS).
		<b>GF10</b>	<b>Good Practice:</b> France has operated a comprehensive register of sources for many years. The Register includes sources of all IAEA source categories which exceeds the categories specified in General Principle 11.
		<b>SF6</b>	<b>Suggestion:</b> ASN should make a formal request to Customs to use appropriate monitoring equipment at entry/exit checkpoints for the purpose of for example detecting orphan sources.
		<b>GF11</b>	<b>Good Practice:</b> Strong measures have been established for ensuring the effective management of disused sources including provisions for the return of sources to their suppliers and financial warranties that address the possible default of these source suppliers.

		<b>SF7</b>	<b><u>Suggestion:</u></b> ASN should offer its support and technical expertise to the Ministry of the Environment regarding the development of appropriate monitoring programmes to detect orphan sources that may be present in scrap metal.
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## APPENDIX IV – REFERENCE MATERIAL PROVIDED BY ASN

[1]	<b>2007 Nuclear Safety Convention</b>
[2]	<b>2007 ASN Annual Report</b>
[3]	<b>2008 ASN Annual Report</b>
[4]	<b>ASN Brochure</b>
[5]	<b>ASN Organisation Chart</b>
[6]	<b>ASN rules of procedure</b>
[7]	<b>ASN Strategic plan 2007-2009</b>
[8]	<b>ASN rules of procedure</b>
[9]	<b>ASN-SFRO Scale</b>
[10]	<b>INES-scale</b>
[11]	<b>IRRS follow-up audit report rev 1 (IAEA)</b>
[12]	<b>Recent_developments_2008 09 30</b>
[13]	<b>IRRS FOLLOW-UP Self-Assessment</b>
[14]	<b>Action Plan</b>

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

- [1] *No. GS-R-1 – Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*
- [2] *No. GS-R-2 – Preparedness and Response for a Nuclear or Radiological Emergency*
- [3] *No. GS-R-3 – The Management System for Facilities and Activities*
- [4] *No. GS-G-1.1 – Organization and Staffing of the Regulatory Body for Nuclear Facilities*
- [5] *No. GS-G-1.2 – Review and Assessment of Nuclear Facilities by the Regulatory Body*
- [6] *No. GS-G-1.4 – Documentation for Use in Regulatory Nuclear Facility*
- [7] *No. GS-R-2 – Preparedness and Response for Nuclear and Radiological Emergencies Requirements*
- [8] *No. WS-R-1 – Review and Assessment of Nuclear Facilities by the Regulatory Body*
- [9] *No. WS-R-2 – Predisposal Management of Radioactive Waste, including Decommissioning;*
- [10] *No. WS-R-3 – Remediation of Areas Contaminated by Past Activities and Accidents;*
- [11] *No. WS-R-4 – Geological Disposal of Radioactive Waste;*
- [12] *No. TS-R-1 – Regulations for the Safe Transport of Radioactive Material TS-R-1*
- [13] *No. Safety Series 115 – International Basic Safety Standards*
- [14] *No. NS-R-1/2 – Safety Requirements of Nuclear Power Plants: Operation and Design*
- [15] *No. NS-R-3 – Safety Requirements of Research Reactors*
- [16] *No. NS-R-4 – Safety Requirements of and Fuel Cycle Facilities*

## APPENDIX VI – ASN ORGANIZATIONAL CHART

