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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

ARGENTINA

Buenos Aires, Argentina

22 August to 2 September 2022

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Autoridad Regulatoria Nuclear
PRESIDENCIA DE LA NACIÓN

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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
ARGENTINA

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Mission dates:	*22 August to 2 September 2022*
Regulatory body visited:	*Autoridad Regulatoria Nuclear (ARN)*
Location:	*Buenos Aires, Argentina*
Regulated facilities, activities, and exposure situations in the mission scope:	*nuclear power plants, research reactors, fuel cycle facilities, radiation sources applications, waste management facilities, emergency preparedness and response, transport, decommissioning, occupational exposure, medical exposure, public exposure and environmental monitoring, interfaces with nuclear security*
Organized by:	*IAEA*

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IAEA-2022

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

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EXECUTIVE SUMMARY

At the request of the Government of Argentina, an international team of senior safety experts met representatives of the Argentina Nuclear Regulatory Authority (ARN) from 21 August to 2 September 2022 to conduct an Integrated Regulatory Review Service (IRRS) mission. The review took place at the Marriott Hotel in the City of Buenos Aires.

The purpose of this mission was to review the Argentine governmental, legal and regulatory framework for nuclear and radiation safety within the competence of ARN against the IAEA safety standards as international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the Argentina counterparts in the areas covered by the IRRS and the national regulatory implications of the COVID-19 pandemic in Argentina.

The IRRS team consisted of 19 senior regulatory experts from 18 IAEA Member States, 3 IAEA staff members, 1 IAEA administrative assistant and 2 observers. The IRRS team reviewed the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection, enforcement; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection; control of medical exposure; public and environmental exposure control; transport of radioactive material; waste management; and decommissioning activities. Facilities and activities with X-rays devices below 1 MW which are under the responsibility of the Ministry of Health and the regulation of NORM under existing exposures were excluded of the scope of the mission. The IRRS mission included discussion of three policy issues, including: Regulatory Implications of the Pandemic Situations; Human Resources Policies and Strategies; and Regulatory Implications of Novel Technologies – Proton Therapies.

The IRRS team conducted interviews and discussions with the staff of ARN. Members of the IRRS team also observed regulatory activities at an operating nuclear power plant, a research reactor, a fuel manufacturing plant, a radioactive waste management facility, a radiation facility, and a hospital. The visits included discussions with management and staff of the facilities. The IRRS team also met the General Secretary of the Presidency of the Nation.

In preparation for the IRRS mission, ARN conducted a thorough self-assessment and prepared a preliminary action plan to address areas for improvement that were identified. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material (ARM) for the mission.

The IRRS team acknowledged the outstanding efforts of ARN to engage in this extensive international peer review. This active participation enabled the IRRS team to develop a broad understanding of the regulatory framework resulting in recommendations and suggestions that should benefit nuclear and radiation safety for all in Argentina.

Over the last 70 years, Argentina has developed a comprehensive and robust regulatory system for nuclear and radiation safety covering facilities, activities, and exposure situations regulated by ARN. ARN is considered a mature and competent regulator with a high level of independence which ensures it is able to fulfil its statutory obligations without undue influence.

The IRRS team identified a good practice in the area of education and training. Indeed, ARN has been implementing an outstanding education and training programme in radiation and nuclear safety for more than 40 years for Latin America and the Caribbean. This is clear demonstration of a long-standing commitment of enhancing and promoting safety globally.

The IRRS team also identified a number of areas of good performance, including:

- ARN's own laboratories and personnel for external, internal and biological dosimetry, as well as radiochemical laboratories, which provide the regulatory body with the capability to make its regulatory decisions, based on its own measurements and radiological safety evaluations, as well as radiochemical laboratories with environmental monitoring laboratories;
- The certification on action protocols against COVID-19 gained by ARN which has helped the regulatory body to effectively discharge its responsibilities while supporting its credibility towards interested parties; and
- The promotion of the new standard AR 10.6.1 rev. 0 to the intended users and the public were made in a very systematic and innovative way, supporting the effective understanding and implementation by the licensees.

In the spirit of continuous improvement, the IRRS mission report includes a number of recommendations and suggestions to improve the Argentina regulatory infrastructure and regulatory practices on matters of nuclear and radiation safety.

The IRRS team considers that the main challenge is the revision or development of several regulatory standards and guides, a time-consuming process where it is questionable whether the present staffing is sufficient for ARN to achieve its goals in a timely manner.

In addition, the IRRS team concluded the following issues are representative of those which, if addressed by the Government and ARN, should further enhance the overall effectiveness of the regulatory system.

Government:

- Establishment of a fiduciary fund for decommissioning, radioactive waste and spent fuel management;
- Completion of the implementation of the national policy and strategy for the decommissioning of facilities and for the management of radioactive waste;
- Development of a national nuclear and radiological emergency plan, a national protection strategy for radiological hazard and strategies for specific aspects.

ARN:

- Establishment of regulatory provisions to consult interested parties, including the public, during the regulatory decision-making process, as appropriate;
- Coordination in the field of regulatory control of medical facilities and services between ARN and the Ministry of Health;
- Establishment of a comprehensive human resources plan to ensure sufficient qualified and competent staff are allocated in relevant areas in accordance with a graded approach to discharge all its responsibilities;
- Completion of the management system with the identification and documentation of the missing processes;
- Establishment of requirements and criteria for termination of the authorization for decommissioning;
- Establishment of a formal process to perform periodically integrated safety assessments by combining the results of review and assessment and inspection to identify trends and draw conclusions on safety of facilities and activities;
- Bringing together the whole range of possible enforcement actions under a comprehensive enforcement policy;

- Implementation of a formalized process to review systematically, and revise, as necessary, standards and guides to keep them up to date and make a special effort to issue those standards that are particularly incomplete or outdated.

The IRRS team highlighted the extended full support and cooperation in the regulatory, technical, and policy issues by all parties in a very open, transparent and frank manner, throughout the mission. Inviting international full scope peer reviews is considered a sign of openness, transparency and commitment to continuous improvement.

At the end of the mission an IAEA press release was issued.

I. INTRODUCTION

At the request of the Government of Argentina, an international team of senior safety experts met representatives of the Argentine Nuclear Regulatory Authority (ARN) from 21 August to 2 September 2022 to conduct an Integrated Regulatory Review Service (IRRS) mission. The review mission was formally requested by the Government of Argentina in December 2016. Due to the pandemic situations in 2020 and 2021, the mission was postponed to 2022.

The purpose of this mission was to review the Argentine governmental, legal and regulatory framework for nuclear and radiation safety within the competence of ARN.

An initial preparatory meeting was held in Argentina at ARN headquarters on 06 - 07 November 2018 to discuss the purpose, objectives and detailed preparations of the review in connection with facilities, activities and exposure situations regulated by ARN and their related safety aspects as well as to agree upon the scope of the IRRS mission. Considering the postponement of the mission, a second preparatory meeting was conducted virtually from 22 to 25 March 2022 to update the arrangements for the preparation and the organization of the mission.

The IRRS team consisted of 19 senior regulatory experts from 18 IAEA Member States, 3 IAEA staff members, 1 IAEA administrative assistant and 2 observers. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection, enforcement; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection; control of medical exposure; public and environmental exposure control; transport of radioactive material; waste management; and decommissioning activities. Facilities and activities with X-rays devices below 1 MeV which are under the responsibility of the Ministry of Health and the regulation of NORM under existing exposures were excluded of the scope of the mission. In addition, policy issues covering the regulatory implications of the pandemic situations, human resources policies and strategies, and regulatory implications of novel technologies – proton therapy, were discussed in the course of the mission.

ARN conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of ARN's self-assessment and supporting documentation were provided to the IRRS team as Advance Reference Material (ARM) for the mission. During the mission, the IRRS team performed a systematic review of all topics within the agreed scope through review of the ARM, interviewed ARN management and staff and conducted direct observations of ARN regulatory activities at regulated facilities.

Throughout the mission, the IRRS team received excellent support and cooperation from ARN's senior management and staff.

II. OBJECTIVE AND SCOPE

The purpose of the IRRS mission to Argentina was to review the national radiation and nuclear safety governmental, legal and regulatory framework and activities within the competence of ARN against the relevant IAEA safety standards in order to report on the effectiveness of the regulatory system and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities, activities and exposure situations regulated by ARN: nuclear power plants, fuel cycle facilities, research reactors, waste management facilities, decommissioning activities, transport of radioactive materials, radiation sources applications, control of medical exposures, occupational radiation protection, radiation protection of the public and the environment. Facilities and activities with X-rays devices below 1 MW which are under the responsibility of the Ministry of Health and the regulation of NORM under existing exposures were excluded of the scope of the mission.

It is expected that this IRRS mission will facilitate regulatory improvements in Argentina and other Member States by utilising the knowledge gained through the evaluation of the Argentine regulatory framework for nuclear safety as well as the experiences shared between ARN and IRRS reviewers, including the good performances and the good practice identified during the mission.

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

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other states with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among states;

j) promoting the application of IAEA Safety Requirements;

k) providing feedback on the use and application IAEA safety standards;

l) providing feedback on the regulatory implications of pandemic situations.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Argentina, a preparatory meeting for the IRRS was conducted from 22 to 25 March 2022. The preparatory meeting was carried out by the appointed Team Leader Ms Marta Ziakova, the Deputy Team Leader Mr Javier Zarzuela and the IRRS IAEA team representatives, Mr Jean-René Jubin, the IAEA Coordinator, and Mr Jovica Bosnjak, the IAEA Deputy Coordinator.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of ARN represented by Mr Agustín Arbor González, President of the Board of Directors of the ARN, other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities, activities and exposure situations would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

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

In addition, the following policy issues were identified to be part of the scope of the mission:

- Regulatory implications of the pandemic situations;
- Human Resources policies and strategies; and
- Regulatory implications of novel technologies – Proton therapies.

Presentations were delivered by the national counterparts on the national context, the current status of regulatory infrastructure in Argentina and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Argentina in August and September 2022.

The proposed composition of the IRRS team was discussed and confirmed. Logistics included meeting and workplaces, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements. ARN confirmed Ms Gabriela Siraky as IRRS Liaison Officer, and Mr Antonio Oliveira as Deputy Liaison Officer.

The ARN provided IAEA with the ARM for the review in June 2022. In preparation for the mission, the IRRS team members reviewed the ARM and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

As the previously assigned team leader was not in position to participate in the mission, Mr Javier Zarzuela was appointed IRRS Team Leader and Ms Carrie Safford as Deputy Team Leader. Mr. Christian Vandecasteele, reviewer of Module 10 on Emergency Preparedness and Response, could not travel and conducted his review virtually.

The initial IRRS team meeting took place on 21 August 2022 at the Hotel Marriott, directed by the IRRS Team Leader and the IAEA Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the IRRS team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission. The host Liaison Officer, Ms Gabriela Siraky, was present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on 22 August 2022, with the participation of ARN senior management and staff, at the San Martín Palace, sit of the Ministry of Foreign Affairs, Worship and Trade. Opening remarks were made by Mr Arbor González, Chairman of the ARN Board, and Mr Javier Zarzuela, IRRS Team Leader. Ms Gabriela Siraky, Liaison Officer, gave an overview of the Argentinian context and main conclusions from the self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Argentina with recommendations and suggestions for improvement and where appropriate, the identification of good performance and good practice. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety. The IRRS team also met the General Secretary of the Presidency of the Nation.

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

The IRRS exit meeting scheduled on 2 September 2022 had to be cancelled, as the Government of Argentina had decreed a national holiday that day because of exceptional circumstances.

An IAEA press release was issued in the aftermath of the mission.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The fundamental safety objective to protect people and the environment from harmful effects of ionizing radiation is set out in National Law of the Nuclear Activities (Act No 24.804), hereafter referred to as Nuclear Act, its Regulatory Decree No 1.390/98 and Act No 25.018, Radioactive Waste Management Act. These laws and decree constitute the core of the legally binding documents that define the policy and strategy related to nuclear safety in Argentina. Article 1 of Act No 24.804 establishes: "Concerning nuclear matters the State will establish the policy and perform the functions of research and development through the National Atomic Energy Commission and of regulation and control through the Nuclear Regulatory Authority." ARN formulates the national strategy to establish and maintain adequate protection of people and their environment against the harmful health effects that could originate from ionizing radiation exposure as a result of activities involving nuclear or radioactive materials. The Nuclear Act sets forth the roles and responsibilities of ARN in the areas of human and financial resources, research and development, policy for radioactive waste management, consideration of social and economic development, safety culture, and a graded approach to safety.

The main elements of the Argentine national regulatory nuclear strategy for safety include the following:

- Issuance of regulations for radiation protection and nuclear safety;
- Assigning primary responsibility for safety to the license holder;
- Ensuring regulatory oversight through review and assessment, licensing, inspections and enforcement activities;
- Ensuring that both personnel of the regulatory body and personnel involved in regulated activities, managing nuclear or radioactive material, are properly trained;
- Implementing education and training centres on nuclear technology, including safety;
- Organizing an international referential training course for professionals in radiation protection and nuclear safety;
- Developing a regulatory approach on radiological safety based on scientific and technical knowledge;
- Contributing to the international development on these matter through active participation in radiological and nuclear safety international fora (IAEA, ICRP, UNSCEAR);
- Appling a "safety goals-oriented approach" in line with IAEA's recommendations; and
- Sharing its experience through participation in relevant radiological and nuclear safety international fora (IAEA, Safety Conventions, ICRP, UNSCEAR, NEA, Ibero-American Regulators Forum).

The Argentina national policy broadly aligns with IAEA fundamental safety principles and the governmental, legal and regulatory framework for nuclear safety, radiation protection and nuclear security is established and applied.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The national legal and regulatory framework for safety allocates responsibilities in the Nuclear Act and its Regulatory Decree, No 1390/98; Management of Radioactive Waste Act; and the ARN regulatory standards. Act No 24.804 establishes the roles and responsibilities as follows:

- The Nuclear Regulatory Authority has the responsibility to develop and enforce regulations on radiological and nuclear safety, safeguards and physical protection;
- The National Atomic Energy Commission (CNEA) is in charge of research and development, decommissioning and radioactive waste management; and

- The Nucleoeléctrica Argentina Sociedad Anónima, (NA-SA) is in charge of nuclear generation.

The policy and strategy for nuclear safety is mainly implemented through ARN's regulations and standards. The Basic Radiation Safety Standard (AR 10.1.1) takes into account a graded approach in the licensing of different type of installations pursuant to classification of material and/or facilities (Class 1 to 3). The classification of installations considers the radiological risk of the authorized inventories of radioactive/nuclear material, the radiological environmental impact, the potential exposures to members of the public and to workers, and the technological complexity of the installations.

The legal framework for nuclear safety further sets forth the implementation of safety assessments, training of personnel, authorizations regimes, control activities and enforcement instruments, and keeping an active participation in international fora. The regulations are periodically revised according to the developments in the field, conventions adopted, and in response to technological evolution.

The legal framework for nuclear safety considers all stages of the life-cycle of nuclear installations: siting, design, construction, commissioning, operation, decommissioning, management of radioactive waste, closure of disposal facilities as well as supervision of disposal facilities after closure. However, the IRRS team identified some areas where the framework needs further improvement which are described below.

The legal framework in Argentina provides a basic structure and process for public involvement in the decision-making process. Decree 1390/98 provides for implementation of Act 24.804, and Decree 1172/03, Access to Public Information, sets forth a framework to strengthen the relationship between the State and the Civil Society, in recognition of the need for a legitimate, transparent and efficient democracy. In particular, Decree 1172/03 places emphasis on the mechanisms that increase the transparency of government acts, allowing an equal access to information and to broaden the participation of society in the decision-making process of the administration. However, as discussed below in Section 3.8, implementation of the Nuclear Act and associated Decrees do not provide regulatory provisions for consultation with interested parties, including the public, on the processes and decisions of the regulatory body, such as the licensing process for nuclear facilities and the development or revision of regulatory guides (see R4 in section 3.8).

In addition, the legal framework sets forth a process for responsibilities and obligations in respect of financial provisions for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities. This framework is broad and sets forth general roles and responsibilities, however, more specific procedures implementing this framework are needed. A discussion on the need for greater clarity in this area may be found in section 1.7, below.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

As an autarkic organization, ARN makes decisions independently and its functions are separated from the functions of other authorities, institutions or organizations engaged in the development of nuclear power or use of nuclear energy, including the production of electricity.

In 1997, Act No 24.804 created and established the present nuclear regulatory body, the Nuclear Regulatory Authority (ARN) under the jurisdiction of the National Presidency, with the responsibility to independently regulate nuclear activity, transferring all staff, resources, equipment and installations from the previous regulatory authority, itself descending from a regulatory branch of the CNEA (operator/promotor). Article 1 of Act No 24.804 establishes that "concerning nuclear matters the State will establish the policy and perform the functions of research and development through the National Atomic Energy Commission and of regulation and control through the Nuclear Regulatory Authority."

The Board of Directors of ARN is responsible for structuring the organization and managing the available resources in order to efficiently fulfil the obligations stemming from Act No 24.804, Article 15, and its Regulatory Decree (N° 1.390/98). Articles 14 and 15 of Act No 24.804 establish the effective independence of the regulatory body in the decision-making process on all those matters concerning their incumbencies, based on the technical competence and knowledge of its staff. ARN reports to the

General Secretariat of the National Presidency, while the utilities report to the Ministry of Economy, Secretariat of Energy. This functional separation demonstrates effective independence of ARN.

ARN is subject to the public control regime of the National Public Administration. Article 22 of the Nuclear Act, paragraph (d), states that one of the functions of the Board of Directors is to prepare annual budgets and to estimate its resources to be submitted to the National Congress through the Executive Power for its approval, along with the general budget of the Nation. Article 23 of the Nuclear Act establishes that ARN shall manage its administrative, financial, proprietary and accounting matters in accordance with the contents of the Nuclear Act, and the regulations issued for such purpose by its Board of Directors.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

Compliance with the standards and requirements of the Nuclear Act regarding radiological and nuclear safety, safeguards, and security, expressly rests with the responsible entities. The legal framework regarding primary responsibility for safety and compliance with regulations is set forth in Article 31 of the Nuclear Act which states, "The responsibility for radiological and nuclear safety, safeguards and physical protection remains unfailingly with the license, permit or authorization holder." While the license, permit or authorization holder may totally or partially delegate the execution of the tasks, the license, permit or authorization holder retains the ultimate responsibility for safety.

In addition, provision 31 of the ARN Basic Radiation Safety Standard AR 10.1.1, provision 23 of the ARN Security of Sealed Sources Standard AR 10.13.2, and criteria 23 of the ARN Licensing of Class I installations Standard AR 0.0.1 establish that any change of the licence holder or the nonroutine practice authorization holder, which could affect, either directly or indirectly, their ability to cope with their safety-related responsibilities requires prior approval of ARN.

The Basic Radiation Safety Standard AR 10.1.1, provision 17, states that provisions of the standards and other requirements of ARN are minimum conditions to be met by a licence/authorization holder, and the fulfilment of such minimum conditions does not exempt the license/authorization holder from its responsibility to take the necessary measures to improve radiological safety. This is included as an obligatory requirement in all licenses or authorizations issued by ARN.

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

The legal and regulatory framework in Argentina assigns to ARN the responsibility for the regulation of nuclear activity on matters of radiological and nuclear safety, physical protection and control of the use of nuclear material, licensing and control of nuclear installations, and international safeguards. ARN is the sole regulatory authority in the nuclear field. In fulfilling its role, however, ARN may need to liaise with other national, provincial or municipal organizations with other competencies for safety. These liaisons involve matters regarding x-rays, non-radiological risks, and security matters, and are implemented on a case-by-case basis through memoranda of understanding, regular meetings or other means of communication. In many cases there are cooperation arrangements or legally binding instruments that formalize the entities' respective roles and responsibilities.

For example, ARN maintains the following agreements:

a) Agreements with security forces for emergency preparedness and response;

b) Agreements with authorities with competence on medical, industrial, and research applications;

c) Agreements with other governmental institutions related to environment and control of water uses;

d) Systems of accounting and control of nuclear material;

e) Import and Export control;

f) National legally binding instruments; and

g) International initiatives to which Argentina has voluntarily adhered.

The legal framework for cooperation and coordination agreements establishes the commitments and responsibilities of the parties and generally demonstrates that there are no gaps or duplication of responsibilities. The IRRS team found that the agreements are a combination of high-level documents that set out general principles of working together in relation to information sharing, incident investigation, and strategic collaboration. In certain cases, the agreements provide specific terms regarding man-hours, budget and specific limitations on scope.

There is a formal agreement for coordination between ARN and the Ministry of Health in the form of a memorandum of understanding (MoU), which covers several areas of coordination. However, the scope of the MoU with the Ministry of Health does not include cooperation in the area of regulatory control for medical exposure, and for the technical assessment and authorization of technical services. The IRRS team found that the coordination could be further improved, in particular in areas covering authorization and inspection of medical facilities and patient protection where both organizations have duties in legislation (see S16 in section 9.9). For example, the roles are unclear in relation to ensuring justification and optimization of medical exposure and registration of medical equipment, in particular in the case of hybrid medical equipment (e.g. PET/CT), where both regulators perform regulatory control of the equipment with different aims. The complexity of the control of these technologies implies that both regulators need to work more closely with the aim to clarify their roles to the regulated entities (for further details please refer to section 9.10). A similar area of sharing responsibilities was noted in transport where the driver training and vehicle standards are jointly regulated by ARN and Ministry of Transport, this is identified in sections 7.8 and 9.8.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN and the Ministry of Health have an MoU covering several areas of coordination, however coordination in the regulatory control is not covered. Considering that both organizations share roles and responsibilities in the regulatory control of the medical facilities and services, there is a need to strengthen existing cooperation.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties".*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 29 para. 4.53 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including: …* *- Liaison with the relevant organization for joint inspections, where necessary."*
R1	**Recommendation: ARN and the MoH should improve coordination in the field of regulatory control of medical facilities and services, and when necessary, implement joint inspection.**

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

The legal framework in Argentina provides for a system to identify existing exposure situations and to establish protective actions (including regulatory actions) to reduce undue radiation risks associated with natural or artificial unregulated sources or with contamination from past activities or events. The Nuclear Act (Act 24.804) designates ARN as the responsible government authority for making the necessary arrangements for the protection of workers, the public, and the environment. ARN establishes the regulatory requirements and criteria for protective actions in cooperation with other authorities. Article 16 (i) of the Nuclear Act empowers ARN to confiscate nuclear or radioactive material that is not under regulatory control and to put it under effective control. ARN also has the authority to require the

closure of installations whenever they lack the proper license, permit or authorization. The Basic Radiation Safety Standard AR 10.1.1, requirement 112, establishes the type of existing exposure situations considered in in AR 10.1.1, due to the presence of radioactive material resulting either from activities in the past (not regulated or regulated in a different regulatory framework) that need a reassessment, or radioactive material resulting from a nuclear or radiological emergency once the emergency situation has been declared terminated.

An important distinction to note is that ARN does not have legal authority to exercise control and regulation of the activities that handle natural radionuclides (except the extraction and processing of natural uranium as part of the nuclear fuel cycle). In accordance with Act 24.804 Article 30, industrial activities that involve Naturally Occurring Radioactive Materials (NORM) are not considered nuclear activities. However, remediation of shut down uranium mining installations is an activity that is regulated by ARN as it is considered a planned exposure situation.

Article 16 (i) of Act 24.804 empowers ARN to seize radioactive materials containing artificial nuclides when the sources have been found to be out of the regulatory control. ARN is likewise empowered to order the preventive closure of installations that lack the corresponding licenses, permits or authorizations, or when a serious breach of the applicable safety regulations is detected.

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

Provisions for the safe decommissioning of nuclear installations, the safe management and disposal of radioactive waste, and the safe management of spent fuel, are found in the Act No 24.804, its Regulatory Decree 1.390/98, Act No 25.018 (National Law on Radioactive Waste Management Regine), ARN Radioactive Waste Management Standard AR 10.12.1, and the ARN Nuclear Power Plants Decommissioning Standard, AR 3.17.1.

Act No 25.018 establishes the responsibilities of CNEA as the competent authority for the management of radioactive waste and irradiated nuclear fuel elements, as well as the responsibilities of license holders (waste producers) until transfer of radioactive waste and spent fuel can be implemented. Waste and spent fuel management must follow pre-established procedures and conditions established in corresponding authorizations issued by ARN. CNEA has established a Programme for radioactive waste management and periodically prepares a Strategic Plan for its implementation.

Decree 1.390/98, which implements Act No 24.804, states that funds for decommissioning of nuclear power plants in the operation and management of their high and medium activity radioactive waste should be created through a fiduciary fund. The National State retains the long-term responsibility, and CNEA is the responsible state organization for the management of spent fuel, as well as for any radioactive waste generated within the national territory. Accordingly, the National Programme for Radioactive Waste Management (PNGRR) was created, and it is to be supported by contribution from the National Treasury. The IRRS team, however, did not find evidence of the creation of a fiduciary fund.

Article 6 of Act No 25.018 also establishes that waste producers must provide the necessary technical and economic resources for the safe management of their radioactive waste. Under present conditions, this article is generally applied for all nuclear activities, including nuclear power generation.

Moreover, Act No 25.018 determines that responsibility of waste producers for the safe conditioning and storage of their radioactive waste shall continue until all the conditions required by CNEA to receive them have been met, and ARN has approved such transfer.

Section 1.1 of Article 1 of the Nuclear Act, No 24.804, addresses research and development in the country, within the framework of the national safety policy and strategy. Pursuant to the Nuclear Act, CNEA, as part of the National Radioactive Waste Management Programme, shall:

1. propose the lines of research and development regarding technologies and methods of radioactive waste management of high, medium and low activity, and

2. plan, coordinate, execute, allocate the necessary funds, and control the realization of research and development projects inherent in the management of radioactive waste.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A fiduciary fund for decommissioning of facilities in operation and management of radioactive waste and spent fuel has not yet been established.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 10, para. 2.33 states that** *"Appropriate financial provision shall be made for: (a) decommissioning of facilities; (b) management of radioactive waste, including its storage and disposal; (c) management of disused radioactive sources and radiation generators; (d) management of spent fuel."*
(2)	**BASIS: GSR Part 5 Requirement 1, Legal and regulatory framework states that:** "*The government shall provide for an appropriate national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This shall include the clear and unequivocal allocation of responsibilities, the securing of financial and other resources, and the provision of independent regulatory functions. Protection shall also be provided beyond national borders as appropriate and necessary for neighbouring States that may be affected.*"
R2	**Recommendation: Although there is financing from National Treasury as provided for in the successive national Budget Laws, the Government should develop provisions to establish a fiduciary fund for securing financial resources for decommissioning, and management of radioactive waste and spent fuel.**

1.8. COMPETENCE FOR SAFETY

Through the Nuclear Act (Act 24.804) the government has established a national policy for building competencies in the nuclear area. Pursuant to Article 2 (b) of Act 24.804, the government assigns CNEA the responsibility to promote the education and training of human resources that requires high specialization for research and development of science and innovative technologies in nuclear applications. Pursuant to Article 16 (l), ARN must establish radiological and nuclear safety standards related to staff working in nuclear installations. It must also grant the licenses, permits and specific authorisations that enable the functions that are subject to ARN regulation. The regulatory system associated to licensing of nuclear activities is focused on two processes carried out in parallel: the licensing of the installation itself and the licensing of installation staff. The common objective of both processes is to guarantee from the beginning to the end of any authorized nuclear activity that radiological safety of the public, of workers and the environment is carried out in accordance with national standards, which are line with the international recommendations.

The government has historically enacted legislation giving support to domestic progress in the nuclear field, including those aspects relative to training of people carrying out activities linked to the uses of ionizing radiation. A regulatory system with detailed individual authorization processes for staff carrying out activities using radioactive materials or ionizing radiation is one of the bases to ensure that nuclear activities are performed with adequate levels of safety, in accordance with current national regulations and international recommendations. A good knowledge of the radioactive sources complemented with an appropriate programme of education and training in radiological and nuclear safety is considered necessary to maintain adequate competencies for workers with different levels of responsibilities.

At present, Individual Licenses and Specific Authorizations are required for personnel of Class I installations and Individual Permits for personnel of other nuclear applications involving lower risk. Not the whole personnel are required to have licenses or permits. Staff in key safety related decision levels requires regulatory licenses, while other personnel shall work under supervision of licensed staff and complying with applicable regulations. As an important part of the process of personnel authorization, ARN assesses the Education and Training Programme submitted by the licensee in compliance with

specific standards and in many cases its personnel participate in the examination boards. Finally, this authorization process includes a peers' evaluation instance through the functions of the Advisory Councils.

Based on faculties provided by the Act No 24.804 ARN has developed a strategy of education and training for personnel with responsibilities on safety, including:

a) Development of a set of national regulatory standards where the education and training requirement for personnel have been clearly established;

b) The IAEA-ARN Long-term Agreement to Support the ARN as "Regional Training Centre in Latin America and the Caribbean for Nuclear, Radiation, Transport and Waste Safety";

c) Offer of two Post-grade Specialization Programmes in "Radiation Protection and Safety of Radiation Sources" and "Nuclear Safety". These programs are given by radiation protection and nuclear safety experts, including professionals from ARN, lecturers from the Faculty of Engineering of the University of Buenos Aires, the CNEA, and professionals from nuclear medicine centres;

d) Offer of a Basic Radiation Protection Course (for technical level);

e) Promoting the participation of National and Regional Universities in education and training programmes through cooperation agreements in radiologic and nuclear safety; and

f) Promoting the participation in education and training programs of professional associations and institutions through cooperation agreements.

Article 2 of the Nuclear Act delegates responsibilities to CNEA to offer the high specialization and training programmes.

Finally, since December 2010, CNEA and ARN are part of the Latin American Network for Education and Training in Nuclear Technology (LANENT), organized by IAEA.

Regarding requirements and provisions for appropriate research and development programs, Section 1.1, Article 1 of the Nuclear Act details the permanent intention of the Argentine government regarding research and development in the country.

Regarding periodic verification of technical competencies of authorized parties, ARN fosters the organization of specialized training and retraining courses by CNEA, professional and scientific societies and academic institutions according to the education needs linked to the universe of radiation sources under regulatory control. For those courses and training centres, the ARN has established mechanisms of recognition to certify fulfilment of the regulatory requirements (for further detail regarding educational and training activities, see Good Practice GP1 in section 2.1).

1.9. PROVISION OF TECHNICAL SERVICES

The government has provided a legal framework for the provision of technical services relating to safety (personal dosimetry, environmental monitoring, and equipment calibration). Act 24.804 Section 16 designates ARN as the regulatory body with the authority to provide these technical services.

Regarding dosimetry, in Argentina there are personal dosimetry laboratories for external and internal radiation and biodosimetry belonging to state bodies or private companies. ARN has conducted personal dosimetry inter-comparisons since 1997 for photons and since 2012 for neutrons. With regard to external personal dosimetry, the ARN Board Resolution No 180/2013 establishes that "individual dosimetry can only be carried out by dosimetry services that participate in periodic intercomparison exercises carried out by entities recognized by the Regulatory Authority." Private companies registered at the National Secretary of Health and the laboratories of official organisms have participated in these exercises. Other laboratories from the Latin American Region have also participated.

In addition, ARN has its own laboratories and personnel for external, internal and biological dosimetry, as well as radiochemical laboratories. They constitute an essential tool in order for ARN be able to take

its regulatory decisions, based on own measurements and radiological safety evaluations, which is recognized by the IRRS team as a good performance.

Regarding equipment calibration, CNEA is the national metrology authority for ionizing radiation. At its National Reference Centre for Dosimetry (CRRD), gamma radiation detectors are calibrated for radiation protection purposes. This service is performed for both users of CNEA and users outside it. ARN has a Calibration Laboratory (LC) where its radiation (gamma and neutron) and surface contamination (alpha, beta and gamma) detectors are calibrated. The LC is accredited by the Argentine Accreditation Agency under IRAM 301: 2005 (ISO/IEC 17025: 2005) and carries out the calibrations according to the provisions of document IAEA SRS 16, Calibration of Radiation Protection Monitoring Instruments.

Regarding environmental monitoring, in accordance with the provisions Article 16 (m) of Act No 24.804 and the ARN Basic Radiation Safety Standard AR 10.1.1, ARN carries out an Annual Plan for Environmental Radiological Monitoring (PMRA) in the vicinity of the nuclear and radioactive installations in the country. Such monitoring is independent and parallel to that carried out by the installation's operators, which in turn is evaluated by ARN. The PMRA is done in agreement with the ARN Guideline AR 14. The ARN radiochemical laboratories provide services for measuring and evaluating the concentration of radionuclide activity in different environmental matrices. Likewise, the regulatory control of the discharge monitoring for liquid and gaseous effluents in nuclear power plants is carried out. Discharge samples can be taken independently and analysed in the radiochemical laboratories of ARN.

Regarding the process for authorization of technical services, ARN does not issue an enabling authorization to the technical services for its operation, but verifies compliance with the ARN Board Resolution No 180/2013 (see S16 in section 9.9).

1.10. SUMMARY

The legal and regulatory framework in Argentina for radiation protection and safety, including the establishment of an effectively independent regulatory authority with clearly defined responsibilities, is comprehensive and in good alignment with IAEA safety standards. There following areas of improvement have been identified:

- Improvement of coordination between ARN and the Ministry of Health in the field of regulatory control of medical facilities and services, and when necessary, they should implement a joint inspection;
- development of provisions to establish a fiduciary fund for decommissioning, and management of radioactive waste and spent fuel;
- completion of the implementation of the national policy and strategy for the decommissioning of facilities and for the management of radioactive waste, closure of disposal facilities, and the establishment of the required research and development programmes.

The IRRS team concluded that having a full scope of its own laboratories and services is an essential tool for ARN to make its independent regulatory decisions, based on its own measurements and assessments of radiological safety, and as such, is an area of a good performance.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The government of Argentina has a long-standing commitment to safety. It is a Contracting Party to relevant international safety conventions as follows:

- Convention on Nuclear Safety (CNS);
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- Convention on Early Notification of a Nuclear Accident or Radiological Emergency; and
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

In the context of Argentina's involvement in international arrangements and assistance in case of radiological and nuclear accidents, ARN is the designated national competent authority following the Articles of both Conventions. It has a Centre for Emergencies Control (CCE) in accordance with the National Contact Point for Alerts and the Operations Manual for Incidents and Emergencies Communications of the IAEA (EPR-IE Comm, 2019), through the Unified System for Information Exchange in Incidents and Emergencies (USIE) platform. ARN participates in the IAEA Response and Assistance Network (RANET) through the ARN Biodosimetry Laboratory in Meetings of Competent Authorities Representatives to share its experience regarding interventions in emergency events and international Convention Exercise (CONVEX) coordinated by the IAEA.

Argentina adheres to the following IAEA Code of Conduct and guidance documents:

- Code of Conduct on the Safety and Security of Radioactive Sources:
  - Guidance on the Import and Export of Radioactive Sources. In connection with this, Argentina has formalized administrative agreements on the import and export of radioactive sources with Canada and the Federative Republic of Brazil,
  - Guidance on the Management of Disused Radioactive Sources,
- Code of Conduct on the Safety of Research Reactors.

Argentina has entered into various multilateral and bilateral agreements and memoranda of understanding for cooperation, as follows:

- Amongst others, the Russian Federation, the People's Republic of China, the Federative Republic of Brazil, India, South Africa, Bolivia, Uruguay, Ecuador, Cuba, Mexico, United Arab Emirates, Saudi Arabia, Italy, Jordan, Libya, Algeria, Vietnam, Australia, United States, Canada and Brazil (complete list was provided);
- As one of the founders of the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) with the aim to contribute and promote radiological, nuclear safety, and physical protection in the Region, Argentina led 9 out of the 21 technical projects that FORO developed, and 5 of them concluded in IAEA supported publications (IAEA-TECDOC). ARN acts as the Technical Secretariat of the FORO;
- Cooperation and mutual assistance in cases of nuclear accidents and radiological emergencies between Argentina and Brazil. Argentina participates as member in various relevant international activities, fora, and networks, for example Nuclear Energy Agency (NEA) of the OECD; IAEA´s Safety Standards Committees on nuclear, radiation, waste, transport safety, emergency prepared and response, and main Commission on Safety Standards. ARN's experts take part in advisory groups such as: International Safety Advisory Group (INSAG); International Nuclear and Radiological Event Scale (INES).

A notable practice in promoting global safety is through Argentina's intense and sustained education and training in radiation and nuclear safety that includes the following:

- 40 years of conducting postgraduate educational courses in radiation protection and nuclear safety within the framework of cooperation agreements between the Nuclear Regulatory Authority of Argentina, University of Buenos Aires-Faculty of Engineering and the International Atomic Energy Agency. ARN manages the "Long-Term Agreement (LTA)" with IAEA since 2008 by which the "Regional Training Centre for Latin America and the Caribbean in Nuclear, Radiation, Transport and Waste Safety" was established. The University of Buenos Aires awards the postgraduate university diplomas of "Specialist in Radiation Protection and Safety of Radiation Sources" and "Specialist in Nuclear Safety". Both courses have been reviewed and updated in accordance with the IAEA standard syllabus and accredited by the National Commission for University Evaluation and Accreditation (CONEAU). The courses include practical training in laboratories of the Education and Training Unit of ARN and of regulated facilities of the medical, research and nuclear fields.
- CNEA and ARN are part of the Latin American Network for Education and Training in Nuclear Technology (LANENT) and have hosted various training courses related to nuclear and radiological safety organized by the IAEA.

In addition, ARN´s laboratories participate in the following initiatives:

- ARN Biological Dosimetry Laboratory (LDB) is part of the IAEA's Response and Assistance Network (RANET) and oversees the Latin American Biological Dosimetry Network (LBDNET). The LDB also participates in WHO Radiation Emergency Medical Preparedness and Assistance Network (REMPAN), BioDoseNet (global network of biodosimetry laboratories), and Coordinated Research Project (CRP) E35010.
- ARN Environmental Control Laboratory is part of IAEA's ALMERA network (Analytical Laboratories for the Measurement of Environmental Radioactivity).

The ARN laboratories for environmental radioactivity measurements, calibration of radiation monitoring instruments, external, biological and internal individual dose assessment, etc. are independently accredited.

In 2015/16, a Practical Arrangement (PA) on Cooperation in the Area of Radiation Safety and Monitoring was signed between the IAEA and ARN. The scope of cooperation is:

- Development and publication of a harmonized approach for managing radionuclide activity concentrations in food and non-food commodities; and
- Development of regulatory guidance on radiological protection in radiotherapy, addressing the potential increase in the risk of secondary cancers. The outputs of this Practical Arrangements were published on-line by ARN and the IAEA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN has demonstrated a long-standing commitment of more than 40 years of enhancing and promoting safety through conducting many education and training activities that involved mainly Latin Americans and the Caribbean and 19 graduates from other Regions, including a Postgraduate Course in Radiological Protection and Nuclear Safety, and several other training courses and workshops for staff of regulatory bodies and for other professional groups, such as the first responders in radiological emergencies or the medical community.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 14 states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
GP1	**Good Practice: ARN's outstanding education and training programme in radiation and nuclear safety that involved Latin America and the Caribbean is considered a good practice in promoting and enhancing safety globally.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

ARN has a particular interest in the analysis and exchange of operational and regulatory experience, both in regional and international levels, and promotes and supports such kind of undertakings. ARN also supports that users of radioactive material and operators of facilities exchange operational experience, both at the domestic and international domain. ARN participates in IAEA Technical Committees and/or meetings to share and exchange updated information on the regulatory areas of its competence and to maintain an adequate harmony between the national regulatory system and the international recommendations. The main channel to receive and send relevant information related to events, corrective actions and lessons learned is through the IAEA/IRS platform.

The following are examples of participation of Argentina in these activities:

- ARN takes part in the CANDU Senior Regulators for countries that operate CANDU reactors, through which regulatory experiences, events, and practices carried out in Member States, are shared;
- Licensee of Nuclear Power Plants (NA-SA) keeps active participation in international organizations of nuclear operators: the CANDU Owners Group (COG), being its member since its creation, and the World Association of Nuclear Operators (WANO);
- ARN is a member of the International Reporting System for Operating Experience (IRS), a platform that grants coordinators of every member country access to its databases in order to become aware of the occurrence of a certain event, exchange information and get a better understanding of the situation. Both results and the lessons learned from these meetings are shared among the ARN specialists;
- ARN is also member of the Incident Reporting System for Research Reactors (IRSRR), an IAEA programme that aims at the exchange of safety-related information on unusual events among members;
- Argentina participates through the NEWS platform (IAEA) for the exchange of information on nuclear or radiological events with impact on safety. This platform applies the INES International Nuclear Events Scale to classify events;
- ARN also participates in the meetings of the programme "International Generic Ageing Lessons Learned" (IGALL); and
- ARN is a member of the Bi-National Nuclear Energy Commission (COBEN for its Spanish initials) with the Federative Republic of Brazil. One example of cooperation was the participation of Argentinean observers during the replacement of the Steam Generators in Angra I NPP in Brazil;
- Annual meetings under the framework of the Agreement with the USA on the Joint Standing Committee on Nuclear Energy Cooperation between Argentina and USA (JSCNEC) are held, where information about nuclear activities in both countries are shared.

Regarding how the experiences are reflected into regulatory measures, the operating licenses require the implementation of an Operational Experience Management Programme and an Operating Feedback Programme. The Operating Feedback Programme takes into account the follow-up of corrective actions of safety significant events that the licensees have to comply with. In the license it is stated that every three months the utility has to summarize all safety related events (relevant and non-relevant), where

actions and improvements are required. When an event is considered relevant to safety, the communication has to be done immediately.

The IRRS team was informed that while in practice, the use of feedback from operating experience and regulatory experience and reporting relevant information and lessons learned in a timely manner were done, however, there is no formal documented mechanism established on this.

With regard to medical exposures, there is no established mechanism for dissemination of lessons learned from unintended and accidental medical exposures related to design flaws in medical equipment to the licensees.

ARN has a procedure P-LCRN-11, Management of relevant events in nuclear power plants, to assess which events may need deeper analysis, using a root cause analysis methodology.

ARN has several websites where information on nuclear and radiological safety can be accessed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no formal mechanism established for utilizing the feedback from operating and regulatory experience. There is also no formal mechanism established to report in a timely manner information and lessons learned from operating and regulatory experience to international knowledge and reporting networks.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 15, para. 3.5 states that** *"To enhance the safety of facilities and activities globally, feedback shall be provided on measures that have been taken in response to information received via national and international knowledge and reporting networks."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 15, para. 3.5A states that** *"Relevant information and lessons learned from operating experience and regulatory experience shall be reported in a timely manner to international knowledge and reporting networks."*
(3)	**BASIS: SSG-46 para 5.274 states that** *"The regulatory body and/or the health authorities could disseminate information on significant events reported to them and on the corrective actions taken, so that other facilities might learn from these events."*
S1	**Suggestion: ARN should consider establishing provisions to use feedback from national and international operating and regulatory experience for all facilities and activities, as well as for reporting in a timely manner relevant information and lessons learned from operating and regulatory experience to international knowledge and reporting networks.**

2.3. SUMMARY

The Government of Argentina is a party to relevant international conventions and adhered to the IAEA Code of Conduct for ensuring protection and safety in the utilization of nuclear energy and radiation for peaceful purposes. It has entered into various multilateral and bilateral agreements.

The IRRS team recognized that ARN's long-standing commitment in enhancing and promoting safety globally through an outstanding education and training programme is a good practice.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

ARN was established with the Nuclear Act in 1997 as an independent and autarkic organization with the mandate to regulate nuclear and radiological safety, nuclear security and safeguards (X-ray equipment and NORM being outside ARN's purview and not within the scope of the Mission). ARN is led by a Board of three Directors which is responsible for issuing main regulatory decisions expressed as "resolutions". The Board defines the organizational structure of ARN. ARN's three core departments with approximately 60% of the total number of staff execute the regulatory control activities for nuclear installations as well as installations and practices involving radioactive materials in medicine, research, industry plus radiological protection measurements. Other units in the organizations are the divisions of regulatory standards and of radiological and nuclear emergency intervention, the departments of legal affairs, of non-proliferation policies and institutional affairs, of administration affairs and resources, and the education and training management unit. Further units perform support functions like human resource, internal audit, quality management, etc. The Board also establishes so-called "activities" which are internally assigned to different organizational elements and are used to focus on specific topics and carry out the corresponding duties, e.g. the "activity" of control of transport of radioactive material.

The Board issues the Institutional Strategic Plan, valid for 4 years, giving the guiding lines and strategic objectives for ARN to reach in order to discharge its duties as regulatory body. On the basis of the Strategic Plan the Annual Budget and Working Plans are drafted by ARN under the lead of the Planning and Management Control Unit to the attention of the Board. In turn, the Board submits the annual budget to the Congress for its approval along with the general budget of the Nation. The approval of the Annual Working Plan is the sole responsibility of the Board: the Annual Working Plan is a very detailed plan of assigned resources and tasks to be carried out by each ARN organizational elements including the "activities". Its approval though somewhat staggered with respect to the annual budget allows the prioritization and allocation of resources according to a graded approach. The resources of the ARN are subject to some constrains and controls common to all the governmental institutions by the Law on Financial Administration and Control Systems of the National Public Sector. The impact of said constraints in terms of budgetary restrictions, administrative restraints or staffing limitations, requires an increased managerial attention in order to consistently prioritize activities and avoid compromising the regulatory effectiveness. The IRRS team was informed that the Board may appeal through the General Secretariat to the President of the Nation for ARN to be exempted from the nationwide restrictions, e.g. from the current ban on recruitment in the public administration, in view of its statutory responsibilities for nuclear safety, security and safeguards.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

ARN is an entity separated from the Central Administration, endowed with its own legal personality and the ability to administer itself while performing a function of the State by express delegation; as such ARN enjoys a high degree of independence. According to the Nuclear Act, ARN has the explicit mandate to enforce corrective actions and/or sanction in case of non-compliances by the authorized parties. In general, being part of the public administration, ARN in its regulatory decisions can be challenged by stakeholders including the public through administrative appeals regulated by the administrative laws (administrative procedure), in a first instance, or by judicial claim against the State (contentious-administrative procedure), in case of rejection of the appeal.

From a legal point of view, ARN is independent from any organization dedicated to the use or promotion of nuclear energy as indicated in the Nuclear Act. ARN reports to the General Secretariat of the National Presidency, while the utilities report to the Ministry of Economy, Secretariat of Energy. Though ARN was born out of a regulatory branch of CNEA, the roles have been clearly separated in the legal framework and there is no interface between the two organizations except that between the regulatory body and an authorized party.

Public administration expenditures are governed by strict guidelines set out in the budget, approved by law, and by the rules set out in the Budget Law of each jurisdiction. The performance of expenses in breach of these rules constitutes a crime against the public Administration, established in the criminal code. Within the budget approved by the Congress, ARN is autonomous in assigning financial resources to the necessary regulatory tasks and activities as instructed by the Board of Directors.

The personnel of the public administration are governed by special rules, different from those that regulate the workers of the private activity. Among others, the Law on Ethics of the Public Function complements the Code of Ethics and states the duties, prohibitions and incompatibilities applicable to all public officials.

For example, in the recruitment of staff, it is required that persons should not have worked for a licensee for at least 3 years before joining ARN. In general, a work contract and a signed declaration may be required, stating that no conflict of interest is present.

ARN has emphasized that the competence of staff is crucial for achieving effective independence in decision making by the regulatory body and has training courses in place for nuclear safety and radiological protection, beyond the instructions related to the working methods and ethics of the regulatory body.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The short-term planning of human resources is done at ARN through the annual work plan (AWP), which includes information on the distribution of resources foreseen for handling the functional units of ARN during the year. A comprehensive human resources plan is not established yet. The IRRS team was informed of the different challenges faced by ARN to acquire and maintain competent and motivated staff in the present competitive market for young professionals. Under the lead of the Human Resources Department several steps have been taken with the goals of a systematic long-term planning and establishing ARN as a modern and attractive employer. Special mention is due to the long discussions with social partners for introducing a Sectorial Working Collective Agreement for ARN staff. Such an agreement is viewed by ARN as fundamental prerequisite for an adequate human resource planning, providing mechanisms for career advancing, annual evaluations, adaptation of salary to performance and skills. It is estimated that the Agreement would be signed into a decree of the President of the Nation by the end of 2022.

ARN recognizes the central role of its employees as the fundamental element in order for the regulatory body to discharge its responsibilities, and has indicated in its current Institutional Strategic Plan, under line IV, the strategic objective of consolidating the organizational structure and staff with increasing levels of professionalization and training. This is even more necessary in view of resources and competence planning for a possible new build in Argentina.

Steps already introduced by ARN are related to the embarking process for new staff, which has been formalized with formal introduction to ARN work methods and ethics and follow-up after the first 6 months of employment. New staff goes through technical trainings and then for the specific functions are instructed with a less formalized, on-the-job training approach. ARN plans to continue fostering knowledge management in all areas of the organization, e.g. by generating a competence map that facilitates the process of staff rotation or reskilling.

Based on the information provided, the IRRS Team concludes that human resources planning with a longer perspective, based on strategies to compensate for the departure of qualified staff would be beneficial; in some areas, additional resources are needed to reduce overtime and improve the effectiveness and resilience of the regulatory body.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN does not have a comprehensive human resources plan with the overarching goal of acquiring and maintaining the necessary qualified and competent resources. ARN currently has only two qualified inspectors in the area of transport, providing no resilience to staff turnover. The division of Regulatory Standards does not have enough resources to revise the regulations and guides as well as develop new ones as foreseen according to ARN's own action plan.*	
(1)	**BASIS: GSR Part 1 (Rev. 1), Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
(2)	**BASIS: GSR Part 1 (Rev. 1) para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions"*
(3)	**BASIS: GSR Part 1 (Rev. 1) para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
R3	**Recommendation: ARN should bring together and complement the existing provisions for human resources management into a comprehensive human resources plan in order to ensure sufficient qualified and competent staff are allocated in relevant areas in accordance with a graded approach to discharge all its responsibilities.**

Policy Issue: Human Resources strategies

ARN has a long-standing approach to maintaining the competence of the organization as well as the capacity building for safety in Argentina. In the late 1970s, ARN set up a postgraduate course for professionals, in Radiological and Nuclear Safety, not only to address national but also international needs. This course was offered to the IAEA, and gained its support for the participation of foreigners. As highlighted in its strategic plan, human resource and competence management has stayed as a top priority for ARN as necessary features to discharge its regulatory responsibilities in an effective manner.

Argentina expressed interest to have focused discussions with the IRRS team on the following topics:

- Assessment of personnel competence level to identify potential gaps;
- Strategies to attract new generation talented people to become regulators.

The main experiences and overall conclusions drawn from the discussion were:

- Competence and human resource management remain a top priority for the regulatory bodies. They need to be proactive in adopting clear and effective strategies to maintain their capability in a long-term perspective;
- Knowledge management, including knowledge transfer between generations, is a key aspect of the competence management within an organization;
- Involvement of experienced staff in drafting regulations, guides and management system documents enable them to incorporate their experience into the regulatory processes.
- The challenges of regulatory bodies to communicate with younger generations were emphasized. New approaches are necessary to reach out to them, including using their preferred communication channels (social media).

- Considering that regulatory bodies are usually non-competitive with industry in terms of salary, innovative benefit packages could be provided to respond to the actual needs and expectations of the new generations (e.g. flexible working arrangements; specific housing, health and/or sport services to the staff; possibility to work at international level, and training and education possibilities).
- Recruitment of foreigners is possible for most of the regulatory bodies despite of some national limitations.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The Board of Directors has the authority to establish advisory bodies when it deems it appropriate in order to get an additional independent opinion. Currently, ARN has two Advisory Councils to the Board of Directors for licensing staff in positions with responsibilities on safety at regulated facilities or practices. Members of the two councils are selected by the Board because of their experience in the different fields (e.g., different medical or industrial application, NPP operation) and may belong to both the ARN and licensees, while ARN staff lead and organize the work of the councils. The opinions of ARN staff and of the councils on licence applications for personnel are transmitted to the Board of Directors, who makes the final decision.

With regards to Technical Support Organizations these are selected on a case-by-case basis, taking into account the subject matter and availability of internal competence and resources. ARN follows a formal process for procurement of engineering, technical or consulting services. Beyond commercial TSOs, ARN has agreements with international ones (e.g. Sandia National Labs, GRS) and national institutions (e.g., the universities UNSAM, UNER, UTN) for obtaining technical or other expert professional advice.

Special care is devoted to avoid conflicts of interest: a formal clause is included in the contracts with the TSOs that the same persons are not allowed to provide technical advice on the same subject to the regulatory body and to the authorized parties. Responsibility for the final regulatory decisions always rests with ARN and cannot be delegated.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

Within the authorization process, there is a clear mechanism for the official communication established between ARN and the licensees which is applicable to all regulated activities. When ARN issues a decision, this is submitted to the licensee by different legally binding instruments, such as official letters or regulatory requirements. Appeal possibilities are clearly set out in the law and regulations. Informal mechanisms of communication, such as technical meetings may be used for achieving a common understanding on technical issues before an official application or request is submitted to ARN. The role of ARN staff in such meetings is to become aware of future issues and explain the applicable standards and regulatory procedures.

In case of the introduction of new regulatory standards, ARN may organize technical sessions in order to explain the content of the new or updated requirements, thus promoting a better understanding and implementation of such standards by the authorized parties (please refer also to Chapter 9). ARN also engages in workshops and meetings with professional societies in order to foster communication with end users and authorized parties.

For NPPs, which have also resident inspector by ARN, the formal communication related to the regulatory oversight with the authorized parties is made at different hierarchical levels, depending on the relevance of the communication and severity of the topic on safety, for example, request for mandatory compliance, routine information, or consultation on technical information.

Incoming and outgoing documentation is treated within ARN´s Management System.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

ARN policies, principles, criteria, and safety objectives are framed by the Nuclear Act and its Regulatory Decree. The ARN Strategic Plan, currently covering 2021 to 2025, details the mission, vision and values of ARN in discharging its regulatory duties. Particular emphasis is given to traceability of ARN's decisions, avoiding subjectivity in the application of laws and standards, as well as transparency of oversight for the authorized parties. In the review and assessment process, ARN decisions are based on cooperation among different evaluation groups on the basis of detailed review of technical reports which is carried out by one or more specialists in the field that are independent of the reports' authors and possess broader competences. With regard to inspections, the inspection teams sent to activities or facilities are composed of at least two persons. In case of findings with potential impact on safety, the team may refer back to ARN's central offices and consult with their section managers.

The current normative corpus of the ARN encompasses 64 regulatory standards and 10 regulatory guides. The development of this normative corpus has been a permanent activity since the beginning of nuclear activities in Argentina. The Argentinian nuclear regulatory system is predominantly based on performance criteria, which provides flexibility to deal with different sets of industrial standards (e.g. from different nuclear suppliers), maintaining the consistency and stability of the regulatory system. Some improvement areas regarding the regulatory standards and guides are addressed in detail in Chapter 9 of the present report.

3.7. SAFETY RELATED RECORDS

The regulatory standards, licenses, and authorizations require authorized parties to maintain appropriate safety records during the installation or practice lifetime. The compliance with such obligations is verified by ARN through regulatory inspections/audits as well as by checking and filing the submitted reports.

For NPPs, the obligation for record keeping, periodic reporting, and notification of abnormal events is part of the operating licence conditions. The conditions specify in detail which safety related records need to be kept and also set out the requirements related to safeguards accounting. Periodic reporting of routine effluents and of safety significant findings is also part of the conditions. For deviations from normal operation further provisions are contained in the licence as deadlines and content of reports.

Records regarding generation and management of radioactive waste must be compiled, updated, managed, and preserved in agreement with the management system. The responsible entity of a facility generating radioactive waste must keep inventories of radioactive waste transferred by the generators of radioactive waste, those stored and disposed, keeping said inventories updated during the operation stage of the repository. At the time of closure of the repository, the responsible entity shall submit all the records to the regulatory body.

ARN has implemented a central registry under its responsibility (NEVADOSIS) for doses received by workers in Class I facilities. This registry includes the information related to facilities where workers have been occupationally exposed, the periods of the monitoring, dose received, specification regarding whether the dose was received in planned or emergency exposure situations and others. The Basic Radiological Safety Standard AR 10.1.1 establishes that the registry of occupational exposure of a worker should be kept until 30 years after the occupational exposure of the worker has ended, but no reference is given regarding the conservation and for maintaining the registry until the worker is 75 years old. Moreover, the same Basic Radiological Safety Standard establishes the information that should be included in the individual records. It is not required that individual records should include, when a worker is or has been exposed in more than one employment, information on the dates of employment and on the doses, exposures and intakes in each such employments. This is only fulfilled in the NEVADOSIS system, implemented by ARN for workers of facilities under Class I.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The national dose registry does not cover all classes of facilities. There are neither provisions for including information on the dates of employment, doses, exposures and intakes in each employment, nor provisions for maintaining the record until the worker is 75 years old.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para 4.63 states that** *"The regulatory body shall make provision for establishing and maintaining the following main registers and inventories: …* *— Records of doses from occupational exposure…"*
(2)	**BASIS: GSR Part 3 para. 3.105 states that** *"Records of occupational exposure shall include: … (c) When a worker is or has been exposed while in the employ of more than one employer, information on the dates of employment with each employer and on the doses, exposures and intakes in each such employment. …"*
(3)	**BASIS: GSR Part 3 para. 3.104 states that** *"Records of occupational exposure for each worker shall be maintained during and after the worker's working life, at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure."*
(4)	**BASIS: GSG-7 para. 7.265 states that** *"Consideration should be given to the establishment of a national dose registry as a central point for the collection and maintenance of dose records…"*
S2	**Suggestion: ARN should consider expanding the national dose registry to facilities of all classes and establishing additional provisions to record and retain all information as required.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

A resolution by the Board of Directors created the division of communication within ARN in 2015. The strategy for communication is part of the Institutional Strategic Plan. The most recent one for 2021-2025 explicitly foresees a strategic line related to communication activities of ARN aiming at consolidating a distinctive institutional image of the regulatory body. In particular, the strategic objectives being followed include ensuring the dissemination of regulatory actions and their understanding by the interested parties as well as the adequate implementation of all obligations deriving from the Law on the Right of Access to Public Information.

Channels for external communications with interested parties are traditional printed media, e.g., brochures, yearly activity reports, but above all the newly relaunched institutional website and social media with ARN presence on Facebook, LinkedIn and a YouTube channel. Emphasis has been put on accessibility of the website and increasing the audio-visual content available to reach a broader spectrum of stakeholders. Recently, a section has been opened for anyone to submit a complaint or concern. The Complaints Channel is a transparency tool implemented by ARN so that any physical or legal person can report to the regulatory body an alleged breach of regulatory standards, and do so anonymously if so desired.

ARN has training and information dissemination programmes for the public around the nuclear power plants. The information provided are mainly the risks stemming from the NPPs operation and the measures to be taken by the population in case of a nuclear emergency. In fact, the public living in the vicinity of NPPs and other interested parties participate actively in emergency drills. Therefore, ARN takes this opportunity prior to each emergency drill to conducts training for the local community and other interested parties, including security forces and local governments.

Relations with the media and journalists are established, for example, ARN is being interviewed in relation to recent events elsewhere in the world, which allowed ARN to resend its main messages in the field of nuclear safety and security.

The regulatory body involves interested parties, including the public, in the development of regulatory standards: ARN publishes the draft regulatory standards in the Official Gazette of the national government, on its official web site, social media and public printed media, to allow citizen participation.

ARN also participates in informative talks and public audiences organized by the local governments around authorized facilities. This was the case in occasion of the license renewal for the Embalse NPP in 2016, when ARN participated and answered questions in a public hearing organized by the secretary of environment of the local government.

The IRRS team was informed that there is no formal consultation by ARN of interested parties, including the public, during the licensing process and for issuing regulatory guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no regulatory provisions for consultation with interested parties, including the public, on the processes and decisions of the regulatory body, such as the licensing process for nuclear facilities and the development or revision of regulatory guides.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.61 states that** *"the government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides"*
(2)	**BASIS: GSR Part 1 (Rev. 1) para. 4.67 states that** *"… In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities, and other interested parties, as appropriate [1]. Interested parties including the public shall have an opportunity to be consulted in the process for making significant regulatory decisions, subject to national legislation and international obligations."*
(3)	**BASIS: SSG-12 para. 2.42 states that** *"The public should be given an opportunity to present their views during certain steps of the licensing process, where appropriate."*
R4	**Recommendation: ARN should establish and implement regulatory provisions to consult interested parties, including the public, during the regulatory decision-making process, as appropriate.**

3.9. SUMMARY

The IRRS team reviewed the responsibilities and functions of ARN and found that it performs its regulatory duties in line with the relevant IAEA safety requirements.

The IRRS team identified some areas of improvement related to the establishment of a comprehensive human resources plan, the dose registry for workers and the consultation with interested parties, including the public, in the regulatory decision processes, as appropriate.

4. MANAGEMENT OF THE REGULATORY BODY

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

In ARN, the leadership for and commitment to safety by senior management is demonstrated by several strategic decisions. The organizational chart of ARN is consistent with the functions set forth in the Nuclear Law and with the operation's needs. The Management System of ARN has been in place since 2005. The mission, vision, values and objectives of ARN are established in the Strategic Plan for the period 2021-2025, and the associated tasks are arranged in the Annual Work Plan (AWP).

ARN´s Senior Management has defined safety as an overriding priority, and it fosters safety culture and behavioural expectations towards a safety goals-oriented approach to regulation.

In the Management System Manual, ARN´s senior management promotes and supports that all personnel are empowered to report his/her concern of safety related problems about technical, human and organizational factors without fear of harassment. In addition, at all departmental levels, questioning and learning attitudes are fostered, as part of the development of a strong organizational culture in ARN.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

ARN senior management has established the goals and strategy in such a manner that safety is as an overriding priority and not compromised by other priorities.

The management system of ARN is supported by the intranet, where its policies, procedures and instructions are managed.

The IRRS team observed that, although some of the elements of a safety policy are in place in the Strategic Plan and some others in the Quality Policy of ARN, the policy itself is not documented in the management system, as it is required in GSR Part 2.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN has elements of safety policies in different places, mainly in the strategic plan. However, there is no unified document that explicitly establishes the organizational safety policy in the management system.*	
(1)	**BASIS: GSR Part 2 Requirement 3, para 4.2 states that** *"Senior management shall be responsible for establishing safety policy."*
(2)	**BASIS: GSG-12 para 3.1 states that** *"Senior management, managers and leaders at all levels of the regulatory body should demonstrate, by their own behaviour, consistent adherence to the values of the regulatory body. This should typically include the following: (…)* *- Establishing and communicating a clear vision for safety, which is elaborated through a safety policy, strategy, plans and objectives, whereby safety is paramount;"*
S3	**Suggestion: The regulatory body should consider developing a comprehensive organizational safety policy in a single document.**

4.3. THE MANAGEMENT SYSTEM

ARN has established and is applying an integrated management system. Although the name of the management system is Quality Management System, the IRRS team noted that in practice it integrates safety, health, environmental, security, quality, human-and-organizational-factor, societal, and economic elements.

The organizational structures, processes, responsibilities, accountabilities, levels of authority, and regulatory body interfaces are specified in the ARN's Management System.

ARN´s management system is aligned with the functions established in the Nuclear Law, regarding nuclear and radiation safety and the promotion of a safety culture.

ARN Resolution No 517/15 establishes the current organizational structure of ARN, including the distribution of responsibilities and functions of the senior management for applying the management system. The interfaces are detailed in each procedure of the management system. The accountabilities of the sectors in ARN are clearly defined in the management system documents.

The IRRS team noted that the documentation of the management system is not fully complete, since there are some processes in practice, e.g., the management of organizational changes, but they are not documented. R5 in section 4.5 addresses this issue.

The documentation of the management system is controlled, and versions are tracked. Documents can only be created and revised by staff with the relevant competence in the matter. All revised documents undergo a re-approval procedure in the same way as for the first release.

The regulatory decision-making process is documented in the management system, including a detailed process flowchart displaying the planned and systematic actions necessary to ensure all requirements are met.

Advisory Councils are established for personnel licensing to provide an independent evaluation of compliance with the requirements associated with applicable regulatory standards and with ARN policy. The Advisory Councils provides their recommendations to the Board of Directors. For further information see section 3.4.

In every case when there is conflict in the decision-making process, the final decision is made by the Board of Directors.

The management system of ARN has been developed and applied using a graded approach based on the magnitude of the risk as well as on the complexity of the authorized parties.

The documentation is issued, controlled, and recorded according to the management system procedures defining the instances for assigning responsibility for the review, control and approval of documents. In relation to the control of the filing/recording of documentation, there is a procedure that establishes the methodology for the control of records, “Documented Information Control Procedure”.

The documentation issued within the framework of the Information System of the Quality Management Unit is available and clearly identified on ARN’s internal website of the organization.

4.4. MANAGEMENT OF RESOURCES

Provisions are in place in the management system to ensure that ARN has in-house, or maintains access to, the range of competencies and resources necessary to conduct its activities and to discharge its responsibilities. Senior Management approves the Annual Work Plan and manages the resources allocated and needed to carry out the activities foreseen in this plan, according to a graded approach.

Annual plans identifying personnel and training needs are developed by heads of departments taking into account the actual competencies existing in their activities and the competencies needed in the future. Senior management regularly supervises the competencies and resources of ARN or internal development, including those which could be obtained externally. In doing so, leadership at all management levels is fostered, along with safety culture, and technical, human and organizational aspects associated with safety assurance are sustained in-house.

When new staff is hired, the practice at ARN is to develop a profile document where the definitions about the competencies required, experience and knowledge requirements are clearly specified on a case-by-case basis.

In 2018, a training was conducted by an external institution (INSTITUTO MADERO), specialized on training for leadership, where ARN staff participated. After completing the training, the participants took an exam and received a certificate of completion.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

Processes necessary for the performance of regulatory core functions are identified, developed, managed and documented in the management system, on the basis of the requirements of the legislation. However, the IRRS team noted that not all processes are identified, documented or properly updated in the management system. Examples are given in the respective sub-sections of this report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Most of the processes are properly identified and documented in the management system of ARN. However, some processes still need to be identified and/or documented in the management system, such as the management of organizational changes, and review and assessment.*	
(1)	**BASIS: GSR Part 2 Requirement 10, para 4.28 states that** *"Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation."*
(2)	**BASIS: GSR Part 2 Requirement 6, para 4.13 states that** *"Provision shall be made in the management system to identify any changes (including organizational changes and the cumulative effects of minor changes) that could have significant implications for safety and to ensure that they are appropriately analysed."*
R5	**Recommendation: ARN should complete its management system to ensure that all relevant processes are identified and documented.**

ARN Resolution No 517/15 establishes the current organizational structure and describes the levels of authority and responsibilities within each area. Regarding the organizational interfaces within the organization, there is a Process Map that presents the interrelations at a high level. Furthermore, the interfaces are detailed in each procedure of the management system.

In ARN's management system, there are guidelines and criteria for the conservation, retention, protection, access and standards associated with records.

ARN is part of the integrated digital information systems of the National Public Administration, namely the Electronic Document Management system (GDE), with features for the systematic heading, numbering, tracking and recording of movements of files.

ARN has developed a set of performance indicators for measuring the effectiveness and efficiency of processes and other management system related activities. The data are collected and evaluated yearly.

ARN specifies the scope and standard of a required product or service and assess whether the product or service supplied meets the applicable safety requirements. ARN retain responsibility for safety when contracting out any project and when receiving any item, product or service in the supply chain.

4.6. CULTURE FOR SAFETY

Safety Culture is fostered in ARN through several means, such as the Induction Course implemented for ARN personnel which communicates safety awareness to staff, providing a basis to develop Safety Culture as an organizational culture. Furthermore, employees of ARN are regularly re-trained, and departmental heads foster meetings with inspectors and technical personnel to enhance their safety culture. Within each management department there is an organizational culture that supports and encourages trust, collaboration and communication.

The Ibero-American Foro of Radiological and Nuclear Regulatory Bodies (FORO), which works in co-operation with IAEA, developed the "FORO Project on Safety Culture in organizations, facilities and activities with sources of ionizing radiation" (2015). In this task, ARN was represented by an expert. In

2022, this document was published as IAEA-TECDOC 1995 (https://www-pub.iaea.org/MTCD/publications/PDF/TE-1995web.pdf).

The FORO document has a special chapter dedicated to Safety Culture in Regulatory Authorities. This chapter describes 10 basic elements that are necessary to achieve a strong Safety Culture. It provides a conceptual framework and guidance for the Regulatory Authority about its internal safety culture. The FORO document on Safety Culture also provides information on how to develop a Programme for the Promotion and Development of Safety Culture and examples of good practices to foster safety culture by the regulatory authorities, taken from the input provided by the FORO member countries.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The effectiveness of the regulatory management system is monitored and measured by the Quality Management Unit (UGC) through quality internal audits and the Planning and Management Control Unit (UPyCG), that has the oversight of internal tasks (Veedurías name in Spanish).

The results are reported to the Board of Directors for evaluations and constitute part of the basis for decision making.

In an integrated way, the ARN procedures and related assessment and verification activities are evaluated and the needs for improvements are identified and implemented.

The UGC annually conducts a quality management assessment for the previous period, with Senior Heads on processes included in the UGC management system. As a result of the quality management system assessment, improvement opportunities, resource needs and any need for change in the management system are determined. In addition, the UPyCG assesses each department, and prepares reports to be considered by the Senior Management based on the results of the monitoring and the oversight of the Annual Working Plan.

External audits are conducted as well by AGN (the external auditor of the national public administration, Auditoria General de la Nación - in Spanish) and SIGEN (the governing body in charge of the internal control system of the national public administration).

All information connected to the measurement, assessment, and monitoring activities are gathered and documented in ARN Intranet.

The ARN manages its non-conformities through procedures defined in the management system, by P-UGC-03 "Management of corrective action requests and improvement opportunities " and P-CNCO-13 "Control of Non-conforming Work, Corrective Actions, Improvement Opportunities and Risk Management for Laboratories".

The IRRS team noted that assessment has not been conducted in ARN on leadership for safety and safety culture as already identified by ARN in its action plan developed in the course of the preparation of the mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN has not yet carried out any assessment on leadership for safety and culture for safety.*	
(1)	**BASIS: GSR Part 2 Requirement 14, para 6.9 states that** *"Senior management shall ensure that self-assessment of leadership for safety and of safety culture includes assessment at all organizational levels and for all functions in the organization. Senior management shall ensure that such self-assessment makes use of recognized experts in the assessment of leadership and of safety culture."*
(2)	**BASIS: GSR Part 2 Requirement 14, para 6.10 states that** *"Senior management shall ensure that an independent assessment of leadership for safety and of safety culture is conducted for enhancement of the organizational culture for safety (i.e. the organizational culture as it relates to safety and as it fosters a strong safety culture in the organization). "*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R6	**Recommendation: ARN should regularly conduct assessments of leadership for safety and of culture for safety at all levels of the organization.**

In the year 2020, IRAM put into effect the standard "IRAM 3820 action protocols against covid-19 in the workplace", with the purpose of certifying the action protocols.

The Head of the Quality Management Unit of the ARN, as a representative member of the ISO in Argentina, became aware of its existence and, together with the quality team, analyzed the possibility of adapting the current protocol to the specific requirements of IRAM 3820. As a result, the proposal to certify the current protocol to ensure the health, trust and safety at work of the stakeholders was transferred to the ARN board of Directors.

At the end of 2020, the ARN received the Certification, which was communicated to all the stakeholders and published both on the ARN Intranet and on its external website, and undergoes control audits by IRAM every six months to maintain the certificate up-to-date.

With this certification, the ARN was able to ensure the continuity of regulatory processes and activities, ensuring the health of the interested parties and setting precedents for having been able to carry out an unplanned certification in the face of an abrupt/unplanned situation.

The IRRS team considered that the certification on action protocols against COVID-19 gained by ARN, which has helped the regulatory body to continue to effectively discharge its responsibilities while supporting its credibility towards interested parties, is an area of good performance.

4.8. SUMMARY

ARN has established and implements an integrated management system. The IRRS team has identified the following areas of improvement:

- Although ARN has individual safety policies in place, it is advisable to have a unified organizational safety policy in the management system;
- ARN has identified and documented most of its processes, but some are not documented in the management system, such as inter alia the management of organizational changes, or review and assessment; and
- ARN has not yet carried out any assessment on leadership for safety and safety culture.

The IRRS team identified a good performance in relation to the certification on action protocols against COVID-19 obtained by ARN.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The Argentine legal framework for the authorization of nuclear and radiation facilities and activities is mainly established under the provisions of the National Law of Nuclear Activities, Act N° 24.804, which states that all individuals and legal persons shall comply with standards issued by the Nuclear Regulatory Authority when developing nuclear activities and shall apply for a licence, permit or authorisation.

AR 10.1.1 Standard classifies the installations and practices within three classes (Class I, II and III), applying a graded approach.

Different types of authorization have to be obtained for the different stages in the lifetime of a facility or the duration of an activity. Class I facilities have several stages during their lifecycle, which are accordingly authorized in several steps, with specific milestones and licenses, permits and authorizations (construction, commissioning, operation and decommissioning). Class II and III facilities are generally authorized in one step (operating licence for Class II facilities and registration for Class III facilities). Only a limited number of standards are available that describe the licensing process for nuclear facilities.

AR 0.0.1 (Class I Installation Licensing) states that "no construction, commissioning, operation or decommissioning of a Class I installation may commence without a prior construction, commissioning, operation or decommissioning licence, as applicable, requested by the Responsible Entity and granted by the Regulatory Authority" and that "prior to the application for a licence, the Responsible Entity shall submit to the Regulatory Authority […] the technical documentation necessary for the Regulatory Authority to assess the radiological and nuclear safety of the Class I installation."

AR 4.7.1, AR 3.7.1, AR 5.7.1 and AR 6.7.1 (respectively "Timeline of documentation to be submitted prior to the operation of research reactors, nuclear power plants, particle accelerators and irradiation facilities") require the applicant to submit a safety assessment prior to the operation of these facilities. Other facilities and other stages in the lifetime of nuclear facilities are not covered by any requirements to submit an adequate demonstration of safety in support of an application for the corresponding authorization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Except for some licensing stages for NPPs, research reactors, particle accelerator and irradiation facilities, and for Class II facilities, limited standards and associated guidelines providing clarity and transparency in the licensing process for applicants are available. In particular, submission of an adequate demonstration of safety in support of an application for the authorization of a facility or an activity at other stages in the lifetime of these facilities or activities is not systematically required.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24 states that** *"The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity."*
(2)	**BASIS: GSR Part 3 Requirement 13 states that** *"The regulatory body shall establish and enforce requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity."*
(3)	**BASIS: SSG-12 para. 2.26 states that** *"The regulatory body should develop regulations for the licensing process of nuclear installations and should provide guidelines for applicants in order to provide clarity and transparency in the licensing process."*
(4)	**BASIS: GSG-13 para. 3.30 states that** *"The regulatory body should issue detailed guidance for applicants on how to notify of the intention to conduct an activity or how to apply for authorization…"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R7	**Recommendation: ARN should supplement its regulatory provisions to provide the applicants with more clarity and better availability of information on all the major aspects to be dealt with at all steps of the licensing process, including that an adequate demonstration of safety should be required to support any application for authorization of all facilities or activities.**

When granting an authorization for a facility or an activity, ARN imposes limits, conditions and controls on the authorized party's subsequent activities. A licence may be revoked by the ARN or surrendered by the licensee.

Licence validity is no more than ten years for nuclear reactors and five years for other types of facilities. Authorizations may have to be reconsidered and/or renewed in the different stages in the lifetime of the facility or the duration of the activity concerned.

The IRRS team observed that while there is no specific ARN process for the authorized parties to appeal against a regulatory decision relating to an authorization, or a condition attached to it, there are general mechanisms in place (e.g., general public administration procedures) to allow an appeal to be made; ultimately, judicial action may be taken against ARN decisions.

Adequate arrangements are in place to ensure that only suitably qualified and experienced persons perform any duties which may affect the safety of operations in nuclear facilities. The competence of individuals having responsibilities for the safety of authorized facilities and activities is verified by ARN (e.g. for Class I facilities, ARN grants "individual licences" and "specific authorizations").

When a new activity or a plant modification is to be performed on a licensed facility, a new authorization may be required, depending on the safety significance of the modification following a graded approach.

The IRRS team noted that appropriate means of consulting interested parties and the public about the processes and decisions of the regulatory body are not in place (see R4 in chapter 3.8).

The IRRS team noted that stability and consistency of regulatory control has been assured during the COVID-19 pandemic regarding authorization. There were no consequences of the pandemic on the authorization system, with respect to authorization for facilities and activities. However, the IRRS team was told that the granting or renewal of some personnel authorization (individual licences" and "specific authorizations") was delayed.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

Argentina has three nuclear power reactors: Atucha I, in commercial operation since 1974, Atucha II (in operation since 2016) and Embalse, in operation since 1984 (the reactor was stopped between 2015 and 2019 before starting its life extension). In addition, the Argentinean Nuclear Power Plant of Modular Elements (CAREM), a prototype design, is under construction at the Atucha site, with a planned electric power of 25 MW.

The set of documents that the applicant must submit in support of an application for a licence is described in AR 3.7.1. "Timeline of documentation to be submitted prior to the commissioning of a nuclear power plant". However, requirements for the content of the safety analysis report have not been included in any guidance (see S9 in Section 6.1.3).

The licence for a nuclear power plant is granted for a fixed period, typically 10 years, after which the licensee has to perform a comprehensive safety review as a pre-requisite for the renewal process. The requirements for renewal of licences are established in mandatory documentation described in the corresponding licence. In general, ARN requires the update of the current licensing basis by enhancing the safety level of the facility as a result of the fulfilment of new requirements.

Design modifications of existing nuclear power plants may require authorization from the regulatory body before being implemented and commissioned, depending on their safety significance and

following a graded approach. The licensee (NA-SA) has established a procedure to categorize design modifications in NPPs according to their safety significance. This procedure has been accepted by ARN.

To ensure full compliance with IAEA standard SSR-2/1 (Rev. 1) and SSR-2/2 (Rev. 1), ARN has planned to develop new safety standards for setting regulatory related to staffing of the operating organization, operational limits and conditions and for management of modifications (see recommendation R14 in section 9.2).

5.3. AUTHORIZATION OF RESEARCH REACTORS

ARN supervises 5 research reactors, 2 of them being critical assemblies. One research reactor is currently under construction (RA-10). Requirements for the authorization of research reactors are established in the ARN standards for Class I facilities (see chapter 5.1). Design of research reactors and critical assemblies are covered respectively by ARN standards AR 4-2-2 and AR 4-2-1.

The IRRS team observed that ARN has no specific requirements dedicated for research reactor site evaluation. Accordingly, requirements SSR -3 Safety of research reactors para 3.4 and 3.5 are not met (for further detail, see recommendation R15 in section 9.3). In addition, there are no regulatory requirements related to the content of safety analysis reports and safety assessments for research reactors (for further detail, see S9 in section 6.1.3).

5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES

Regulatory requirements for the licensing of fuel cycle facilities are established in ARN standard AR 0.0.1 Class I Installation Licensing. Rev. 01. The IRRS team noted that, although the standard requires the applicant to submit the technical documentation for assessment to the Regulatory Authority, there is no regulatory standard or guidelines on the format and content of the technical documentation (see S9 in section 6.1.3), except for the plan of radiological environmental monitoring, facility emergency plan and facility decommissioning plan. ARN includes in the licence conditions the list of mandatory documents that should be maintained up-to date by the licensee (safety report, management system manual, operation manual, maintenance manual, code of practices (including the monitoring plan and the emergency plan), preliminary decommissioning plan) and submitted for licence renewal. As it was mentioned above, no guidelines were identified on licensing procedure, sequences of required actions, and decision-making criteria (see R7 in section 5.1).

5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

In accordance with the general regulations described in section 5.1 for radioactive waste management of Class I, the following licences are required:

- construction licence, that is issued against the acceptance of the Preliminary Safety Analysis Report, focused on the requirements on design, the design authority, and responsible entity;
- commissioning licence, with (but not limited to) a Safety Analysis Report on the “as built” design, in a transition situation towards operation, which is most of the plant life;
- operating licence, issued against (but not limited) the “as tested” Safety Analysis Report;
- decommissioning licence, issued considering other documents, as the Final Decommissioning Plan.

The IRRS team was informed that classification of a facility as Class II or III (see section 5.1) depends on their radioactive inventory. The documentation to support the application for a licence for a radioactive waste management facility of these types takes a reference to what is described in Standard AR 5.7.1 “Chronogram on the documentation to be presented prior to the operation of a particle accelerator”, and AR 6.7.1 “Chronogram of the documentation to be presented prior to the operation of an irradiation industrial plant”. The application of these standards follows a graded approach.

ARN’s instruction IRU-SPRIP-01 R 01 describes the content of a Safety Assessment Report for a general radioactive waste management installation. That content includes the consideration of detailed

information about the site, the facility itself, inventory, safety and scenarios covering normal situations and different probable events.

The IRRS team was informed that the operating licence shall be renewed every ten years in the case of reactors and five years for other class I and II installations, or when a safety issue requires it to be updated. As for other type of facilities, the regulation does not consider the decommissioning issues during the design of the radioactive waste management installations (see S5 in section 5.7).

5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

All practices involving the use of radiation sources require an authorization unless they are covered by an exemption.

The following practices can be exempted from regulatory control by ARN:

- Any practice for which it can be demonstrated that it is not conceptually possible to originate an annual effective dose higher than 10 μSv;
- Practices with low probability scenarios in which the effective dose does not exceed 1 mSv in a year.

While most of these authorizations are issued primarily by ARN, authorizations for the use of x-ray generators are issued by the Ministry of Health and are thus outside the scope of the IRRS mission. The practices that are regulated by ARN are divided into 3 classes, according to a graded approach, and taking into account the radiological risk associated with the facility or practice, the environmental radiological impact, the potential consequences, occupational doses, as well as the complexity of the activities:

- Class I practices outside the nuclear fuel cycle include irradiation installations, radioactive source production plants and installations for temporary storage of radioactive sources;
- Class II practices include teletherapy installations with medical linear accelerators or cobalt sources, brachytherapy and nuclear medicine installations, gamma radiography, use of nuclear gauges, well logging installations and transfer of radiation sources; and
- Class III practices include in vitro diagnosis (radioimmunoassay) and other uses of sealed and unsealed radioactive sources of very low activity in research, teaching, or other applications.

Whereas Class I practices involve a multi-stage authorization according to the facility life cycle (construction, commissioning, operating, decommissioning), most radiation source use falls under Class II and III practices, that are generally authorized in one step. For Class II practices, a licence is required. For Class III practices, Registration is used.

Authorizations for use of radiation sources associated with Class II and III practices are valid for periods of 5 years (licences and registrations). After this period, they are subject to renewal at the request of the applicant. Authorizations may also be amended or revoked. The authorizations cannot be transferred from one legal person to another; therefore, if an authorized party changes its legal person, the authorization expires and a new one must be obtained to carry out the practice, ensuring that the new legal person establishes the same commitments to safety of the radiation sources.

For Class II practices, the applicant must appoint a Radiation Protection Officer (RPO) that has a personal licence issued by ARN. This allows ARN to verify the competence of individuals having responsibilities for the safety of authorized facilities and activities.

Prior to obtaining a licence for a practice, the applicant has to prepare and submit to ARN documentation that demonstrates compliance with all the regulatory requirements regarding radiological and nuclear safety, physical protection and safeguards. The scope and details of these documents are based on the classification of facilities/practices following the criteria established, namely in the Basic Safety Standard (AR 10.1.1). However, it was noted that the scope of the safety assessment is limited (see S10 in section 6.6).

On its website, ARN has published further guidance on the format and contents of the documents to be submitted by the applicant in support of an application for authorization. This guidance covers gamma radiography, other industrial applications, nuclear medicine, radiotherapy, transport, import/export of sources.

The authorizations issued by ARN establish limits and conditions that the authorized party must comply to ensure safety, that include limits on the activity of materials that are used and conditions on authorized discharges, as applicable.

ARN performs administrative control, through authorization, of all imports and exports of radioactive material in combination with Customs, regardless of the category of sources. Argentina has adhered to the IAEA's Code of Conduct and Import/Export Guidelines for radioactive sealed sources.

For transfers of sealed radioactive sources between authorized parties, an authorization is not required, but ARN has to be notified, and this information is inserted into the SIRFRAR information system, allowing it to keep track of each radioactive source along its life cycle.

There are provisions in the legal framework preventing the transfer of sources to an unauthorized party. If the intended recipient of the source does not have an authorization, or has an authorization that does not cover the source that is to be received, then it must obtain a licence or request a modification to its existing licence before the transfer takes place.

When radioactive sources have no foreseen subsequent use for a period greater than six months, the authorized party must request ARN for an authorization to adopt one of the following alternatives, as appropriate: re-export, transfer to other authorized party, storage in custody or management as disused radioactive source or radioactive waste. In cases where radioactive materials are found to be out of regulatory control, the Nuclear Act empowers ARN to seize them. Thus, when an orphan source is detected the ARN ensures its management, safe custody and disposal through the National Radioactive Waste Management Programme.

The IRRS team noted in the ARM that Argentina produces Co-60 sealed sources. The Co-60 facility inventory is reported to ARN at least once a year and is permanently available at the facility. The current information system (SIRFRAR) contains detailed data on sources associated with class II and III practices, and is kept regularly updated through the process of authorization. However, the information on sources produced (e.g. in Class I practices that are not part of SIRFRAR) is kept by the facility and sent to ARN only through periodic (yearly) reports. Aside from this periodic communication, ARN may also verify these inventories when carrying out inspections of licensed facilities (usually four inspections a year). This presents ARN with only regular "snapshots" of the sources associated with class I practices, instead of the up-to-date information that is kept for Class II and III practices, derived from the authorization procedures. It was noted in the reference materials that ARN is planning to have a comprehensive information management system, including a full national register of radioactive sources and radiation generators regulated by ARN. This would allow ARN to have full, up-to-date information on all sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The data base (SIRFRAR) does not include information on sources associated with Class I practices. For these practices, ARN gets information through periodic reports.*	
(1)	**BASIS: GSR Part 3 Requirement 3, para. 2.35 states that** *"The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to facilities and activities. These records shall include:* *— Registers of sealed sources and radiation generators; (…)"*
S4	**Suggestion: ARN should consider developing a comprehensive national register of radioactive sources and radiation generators under its regulatory oversight.**

5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

The decommissioning of Class I facilities requires a licence granted by the ARN. For NPP, the AR Standard 3.17.1 "Decommissioning of Nuclear Reactors" establishes the criteria for safe decommissioning of this type of facilities. In accordance with this Standard, the operator is required to submit a decommissioning plan. While the scope of AR Standard 3.17.1 is power reactors, its application to other installation is possible applying a graded approach. The IRRS team was informed that the scope of this standard will be modified to extend it to all Class I facilities and will be updated.

The IRRS team was informed that standard AR 3.17.1 is also applied using a graded approach to Class II and Class III facilities.

A preliminary decommissioning plan shall be presented when applying for the operating licence, and afterwards, it shall be presented with every renewal of the licence: ten years for NPP, and five years for other type of facilities, or when a safety issue requires an update. This plan must be updated according to a defined schedule and in the light of the operating experience and technological advances developed, incorporating modifications made to the plant, incidents and abnormal events, regulations in force, etc., until the time of the request for the decommissioning licence, when the final decommissioning plan must be submitted. The IRRS team was informed that the operation licence for Class I facilities requires the submission of this final decommissioning plan one year before the final shutdown of the facility. For Class I radioactive and fuel cycle facilities, the operating licence requires the submission of a final decommissioning plan six months prior to the proposed decommissioning date. The IRRS team was informed that in the ARM Summary report, there is an error on page 90, and what is pointed out as the preliminary decommissioning plan, is in reality the final decommissioning plan.

ARN instruction IRU-SPRIP-01 R 01 "Content of the decommissioning plan of an installation" describes the content of this decommissioning plan. This instruction applies to both preliminary and final decommissioning plan, in what is applicable depending on the operational evolution of the facility.

The IRRS team was also informed that besides this decommissioning plan, the mandatory documentation for the operation licence shall be presented updated for its application to the decommissioning stage of the facility.

Regarding the consideration of decommissioning aspects at the design stage of facilities, the IRRS team was informed that ARN has internal documents to define the content of the Safety Report required for nuclear power and research reactors in Standard AR 3.7.1 "Chronogram on the documentation to be presented prior to the commercial operation of a nuclear power reactor". According to these internal documents, chapter 19 of the Safety Report shall contain information on the criteria to be established in the design of the facility to facilitate its decommissioning. On the other hand, chapter 19 shall contain information on the foreseen operative practices to facilitate decommissioning, such as reduction of activation in materials, reduction of contamination and the maintenance of records of the facility operation.

Requirements to ensure that key staff are retained, and that institutional knowledge is maintained, are included in AR Standard 3.17.1 and AR Standard AR 0.11.1 "Licensing of Class I installation personnel".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no provisions regarding the incorporation, at the design stage, of features to facilitate the future decommissioning of facilities other than nuclear power and research reactors.*	
(1)	**BASIS: GSR Part 6 para. 7.1 states that** *"The regulatory body shall ensure that the licensee takes decommissioning into account in the siting, design, construction, commissioning and operation of the facility, by means which include features to facilitate decommissioning, the maintenance of records of the facility, and consideration of physical and procedural methods to limit contamination and/or activation."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 6 para. 7.3 states that** *"For a new facility, planning for decommissioning shall begin early in the design stage and shall continue through to termination of the authorization for decommissioning."*
S5	**Suggestion: ARN should consider developing provisions regarding the incorporation, at the design stage, of features to facilitate the future decommissioning of facilities other than nuclear power and research reactors.**
Observation: *ARN has not established requirements and associated criteria for the termination of the authorization for decommissioning.*	
(1)	**BASIS: GSR Part 6 para. 3.3 states that** *"… The responsibilities of the regulatory body shall include: establishing requirements and criteria for termination of the authorization for decommissioning and especially when facilities and/or sites are released with restrictions on their future use"*
S6	**Suggestion: ARN should consider establishing requirements and criteria for termination of the authorization for decommissioning.**

5.8. AUTHORIZATION OF TRANSPORT

ARN is the competent authority (CA) for issuing approvals and validations for transport of radioactive material for all modes of transport. The regulations governing transport apply a graded approach and the aspects of radioactive materials transport involving the higher hazards are regulated by a permissioning regime in which certain designs and activities require prior CA approval.

Compliance is required in Argentina with all the approvals identified by the IAEA safety standard SSR-6, which are included in the regulations in force for each mode of transport (AR 10.16.1, IMDG code and the ICAO Technical Instructions for land, sea and air respectively).

Organisations apply to ARN for CA approval for new designs, renewal of existing approvals, validation of overseas approvals or modifications to approved designs of transport packages or materials. The approval process is well defined and provided on the ARN website with instructions and links to guidance and appropriate forms.

The process starts with the completion of a form, specific to each type of application, which provides the CA with details of the application and identifies information required for the application to be processed. Evidence of package/material compliance is required to be presented in a safety report, guidance is provided on the structure and content of this report. For modifications of existing approvals ARN requests an initial description of the modification before determining the information that is required.

The process of approval usually includes a range of technical assessments and an inspection. The output of the approval process is a certificate of approval, issued by ARN for normally a five-year period, in accordance with the requirements of SSR-6, as detailed in AR 10.16.1. Certificates are signed by either the President of the Board of Directors (for new approvals and special arrangements) or by an authorised person for renewals/modifications.

In addition to the SSR-6 required approvals for packages and materials the ARN President of the Board of Directors has issued a resolution that Type A, IP-2 and IP-3 package designs must be submitted for a compliance assessment prior to use. The process followed is similar for that of package approval, but a certificate of compliance is issued instead.

5.9. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

For occupational exposure the authorization process implemented by ARN is consistent with what is described in section 5.1. In particular, the regulations require from the applicants to describe and to demonstrate that there are arrangements in place for implementing an effective protection of workers.

These requirements include the definition of the operating organization chart (composed by duly trained workers, some with individual license and specific authorizations or permits issued by ARN). This chart clearly defines the person directly responsible for radiological and nuclear safety, as well as with the compliance with the License conditions, standards and requirements including workers occupational exposure. The chart also defines the radiation protection officer. Specific regulations and guides require to demonstrate that workers have been trained and certified as appropriate.

The documents provided by the applicants should include, in case where applicable, the copy of the contract with a dosimetry laboratory which must comply with the regulatory requirements.

The appropriate knowledge, training and psychophysical aptitude is assessed for workers of higher risk facilities by issuing individual licences and permits. Appropriate training and knowledge should be provided by homologated institutions.

The required "Code of practices" (Código de prácticas) describes, amongst other, procedural and technical arrangements for the designation of controlled areas and supervised areas, and the programs for personnel monitoring and for monitoring of the workplace. It also describes a color code for grading and informing about the level of the expected risks in controlled areas. Information and specific procedures are required as appropriate regarding the radiation monitors and individual protection means needed for the operations.

As part of the authorization process the regulatory body commonly requests from applicants to implement additional measures to reduce expected doses as reasonably achievable even when those are estimated to be under 5 mSv. Nevertheless, the existing regulations regarding the optimization process should be revised or further developed (see R18 in section 9.9).

5.10. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

Responsibilities for the regulation of medical exposures in Argentina are divided between ARN and the Ministry of Health. Authorizations for nuclear medicine and radiotherapy practices is issued by ARN, while the medical x-rays and patient protection activities are under the jurisdiction of National and Provincial health authorities. ARN has published regulatory Standards AR 8.2.1 to AR 8.2.4 specifying the authorization requirements for radiotherapy and nuclear medicine practices. All research programmes involving medical exposure of individuals have to be authorized by the corresponding federal or provincial health authorities, ethics committees or National Administration of Medicines, Food and Medical Technology (ANMAT).

Education and Training requirements for issuance of individual permits related to medical applications are established in the regulatory standards AR 8.11.1-Rev 2, AR 8.11.2-Rev 2 AR 8.11.3-Rev 0. There are around 35 training courses for health professionals for training in specific techniques of medical exposure (see GP1 in section 2.1). Operation with radioactive material or ionizing radiation for medical exposures can be carried out only in the presence of a minimum number of trained personnel and with a valid individual permit.

In radiological medical practices regulated by ARN, Basic Safety Regulatory Standard AR 10.1.1- Rev 4, establishes responsibilities on justification of medical exposures. However, ARN informed the IRRS team that Justification of medical exposures and patient dosimetry is in the domain of the Ministry of Health, and hence are not included in the scope of the IRRS review. The regulatory standard AR 10.1.1-Rev 4 requires that in all medical exposures the radiological safety shall be optimized. The Standards specify the requirements on radiation protection of pregnant and breast-feeding patients, quality assurance of medical equipment and calibration of measuring and monitoring instruments. However, dose constraints for carers and comforters and for volunteers in biomedical research involving ionizing radiation sources, diagnostic reference levels (DRLs) for diagnostic procedures are not established.

ARN Standards for medical exposures broadly comply with the IAEA Safety Standards requirements. However, several requirements need to be addressed (see Recommendation R13 in Section 9.10). Standard on "Radiation protection and safety in medical uses for ionizing radiation" has been identified for development and issuance by ARN. ARN should take into account the requirements in IAEA GSR

Part 3 and the associated guidance in IAEA SSG-46 in formulation of the above Standard. The Ministry of Health, through National Administration of Medicines, Food and Medical Technology (ANMAT), authorizes the medical equipment as well as radio pharmaceuticals that may be used in Argentina. The suppliers /importers of medical equipment are authorized by National Administration of Medicines, Food and Medical Technology (ANMAT), and are required to obtain registration of the product in the Registry of Producers and Products of Medical Technology (RPPTM) of ANMAT. Mechanism needs to be established through co-ordination between ARN and ANMAT, for dissemination of lessons learnt from unintended and accidental medical exposures due to design flaws in medical equipment (see S1 in section 2.2).

Policy Issue: Regulatory Implications of Novel Technologies - Proton Therapy

ARN received the Preliminary Safety Report from the Argentine Proton Therapy Center (CeArP) of the National Atomic Energy Commission (CNEA), for the facility of a proton therapy centre consisting of a proton accelerator cyclotron of up to 230 MeV, two treatment rooms with their corresponding gantries and a research laboratory.

ARN faced challenges in licensing this facility, due to the complexity of the facility and associated processes and as this type of installation is new in Argentina and in the region of Latin America and Caribbean.

The host country expressed interest in having focused discussions on the following topics:

- How the flexibility in the regulatory system can be reflected in this type of installation, in particular regarding the classification of the facility and personnel licensing?
- Which changes in the infrastructure (e.g., laboratories) are needed to ensure proper control of this type of installations, considering the need to be able to conduct the full scope of measurement (individual and workplace monitoring and calibrations) for energies significantly higher than those currently existing in the country?

The policy discussion highlighted the following key items:

- As for any other novel technology, establishing adequate regulatory control for proton therapy facility is a challenge for safety regulators;
- The proton therapy facility, considering the complexity of facility and associated processes, typically is classified in the highest Class 1 facility;
- Close cooperation with neighbouring country that operate similar facility or support from IAEA through all stages of the licensing process, in particular for verification of the shielding calculation, the design and operation of the facility, is of crucial importance;
- The idea of considering issuance of licenses with multiple hold points (e.g. Beam extraction in small steps, along with radiological survey of the facility), rather than as a single stage;
- The need for active cooperation between the supplier, operator and regulatory body, including regular exchange of information and plans (e.g., training of operators) is highlighted;
- Visits to similar facilities that are already in operation and to supplier sites have proven to be useful for regulatory body staff;
- The permanent presence of the vendor team at the facility to provide the technical support has shown to be advantage, especially at the beginning of the operation of the facility;
- Maintenance and technical assistance supplied by the vendor is crucial in these type of installations during operation of the facility. Consequently, the regulatory body should pay particular attention to the arrangements and contract between supplier and operator;
- For specific technical services that are not available in the country and are needed for regulatory control, the regulatory body may consider authorizing the available providers from a region;

- TECDOC 1891 on Regulatory Control of the Safety of Ion Radiotherapy Facilities was reported to be useful.

5.11. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

There were no outstanding issues found by the review team on the authorization of public exposure.

The Basic Radiological Safety Standard AR 10.1.1-Rev. 4 establishes the requirements for the protection of people and the environment against the harmful effects of ionizing radiation.

Regarding radiation safety, the Responsible Entity shall ensure that the safety assessment considers the exposure of the public. Dose limits are specified for public exposure considering the dose in the representative person and compliance to these limits is verified. ARN has established requirements and reviews the optimization of protection and safety for situations subject to public exposure.

ARN has specific regulatory standards to establish criteria referring to restrictions and dose limits for the public for discharges of radioactive effluents. Regarding operational restrictions, ARN establishes the authorized discharge values for each Class I installation, and they are included in the corresponding licensing documentation.

Regarding environmental monitoring, it is the obligation of ARN to assess the radiological environmental impact of any activity that it licenses, including monitoring and assessing the possibility of environmental damage that may come from the licensed nuclear activity. ARN has developed its own independent radiological monitoring programme around those installations with potential impact and requires the responsible entities of Class l installations to present an environmental radiological monitoring program. These results are sent periodically to ARN, and then evaluated and compared with their independent programme. The summary and conclusions of the annual independent environmental monitoring plan performed by ARN are accessible to the public through the website.

Regarding consumer products, Standard AR 10.1.1-Rev 4 establishes the requirements that suppliers of consumer products shall meet to ensure the protection of the public: suppliers of consumer products shall ensure that consumer products are only made available to the public if their use has been justified and exempted from any requirement of regulatory regulations or that the Regulatory Authority has authorized their supply to the public. Regulatory Guide AR 6 establishes generic exemption levels that apply. Import and storage in quantities that exceed the exemption values require an operation record.

Regarding existing exposure situations, remediation actions shall be justified, and radiological safety shall be optimized. Remediation actions shall be authorized by ARN and shall be commensurate with the radiological risk associated with the existing exposure situation, prioritizing the public whose doses exceed the reference level. In this case, the reference level for the effective annual dose in the representative person is in the range of 1 to 20 mSv.

In situations of existing exposure due to exposure to radionuclides in commodities such as building materials, food, feed and drinking water, the reference level for the annual effective dose in the representative person is 1 mSv.

5.12. SUMMARY

The Argentine legal and regulatory framework for the authorization system for nuclear and non-nuclear facilities and activities is mainly established under the provisions of the Nuclear Act. The regulatory framework is well developed and implemented, especially for Class II facilities, and includes consideration of a graded approach. Existing standards are, in general, in line with IAEA safety standards.

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

– supplementing regulatory provisions to provide the applicants with more clarity and better availability of information on all the major aspects to be dealt with at all steps of the licensing process;

- the means of consulting interested parties and the public about the processes and significant decisions of the regulatory body are not in place, including regarding the licensing process;
- regarding NPPs, the need to update ARN guidance to ensure full compliance with IAEA safety standard SSR-2/1 (Rev. 1) and SSR-2/2 (Rev. 1);
- the development of a comprehensive national register of all radioactive sources and radiation generators under its regulatory oversight;
- the development of provisions regarding the incorporation, at the design stage, of features to facilitate the future decommissioning and dismantling of facilities other than nuclear power reactors;
- the establishment of requirements and criteria for termination of the authorization for decommissioning.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

Under the Nuclear Act, ARN is empowered to grant authorizations and licences to facilities and activities. Within this framework, ARN performs review and assessment of documentation submitted by the licensees in support of applications for an authorization or a licence at different stages of the licensing process, depending on the type of facility or activity. The facilities and activities are classified according to Standard AR 10.1.1 following a graded approach. By this categorization, the sort of technical documentation, its scope and level of detail should depend on the radiation risks associated with the facility or activity.

The IRRS team was informed that, in practice, scope and level of detail of the information submitted to ARN for review and assessment depends on the radiation risks associated with the facility or activity. However, the IRRS team concluded that this aspect has to be addressed in ARN's framework in a clearer and more formalized manner (Suggestion 7 in Section 6.1.1 addresses this issue).

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The required documentation is submitted to ARN for review and assessment prior to granting an authorization, to demonstrate compliance with nuclear, radiological, transport and waste safety, physical protection and safeguards requirements. Once the operating license is granted and the facility begins commercial operation, additional documentation is submitted to ARN as per the licence conditions specified by ARN in the operating license of that particular facility. The documentation submitted can be classified into routine evaluations and non-routine evaluations. Routine evaluations contain the assessment to demonstrate compliance with the conditions of the operating license. On the other hand, non-routine evaluations are those that are carried out based on proposals for modifications in the mandatory documentation or plant systems and components relevant for safety, significant deviations in the reference operating conditions or as a result of inspections, audits and assessment of routine evaluations carried out by ARN.

The IRRS team observed that although some guidance for ARN staff to perform review and assessment of routine and non-routine evaluations is available in the form of procedures P-CCNO-10 and PCRNO-11, a comprehensive guidance for reviewing major licence submissions from nuclear installations, such as the Safety Analysis Report (SAR), is not available. The IRRS team was informed that a review and assessment plan with its corresponding procedures has not been developed for performing the review and assessment function by ARN. Additionally, a formalized structure for co-operation with other regulatory authorities is also foreseen, aiming to improve the review and assessment process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Comprehensive guidance is not available for ARN staff to perform review and assessment of licensing documents, including the safety analysis report, submitted in the licensing stages of all nuclear installations (e.g. construction, operation and decommissioning).*	
(1)	**BASIS: GSG-13 para. 3.191 states that** *"The regulatory body should provide internal guidance for its own staff on the procedures to be followed in the review and assessment process and on the safety objectives to be met. Internal guidance on specific topics for review and assessment should also be provided, as necessary".*
S7	**Suggestion: ARN should consider developing comprehensive guidance for its staff to review and assess licence applications submitted for all nuclear installations and radiation facilities.**

Argentine regulations AR 10.1.1 classify nuclear facilities and activities (installations and practices) within three classes, Class I, Class II and Class III according to the associated radiological risk. Using this categorization, the type of technical documentation, its scope and level of detail should depend on the radiation risks associated with the facility or activity. The IRRS team was informed that according

to this classification, the reviews and evaluations for different stages of licensing of an installation are performed. However, the IRRS team observed that although the concept of application of graded approach is present, the practical application of a graded approach is not described in the management system. The IRRS team observed that there is a need for ARN to prescribe the methodology for application of graded approach to review and assessment process in a management system document.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The frequency, scope and depth of the corresponding review and assessment processes are determined according to the risk involved, however the ARN's management system does not include, in practice, any provision to apply a graded approach in the review and assessment process.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Para 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(3)	**BASIS: GSR Part 1 (Rev. 1) Para 4.40 states that** *"The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process (initial review, subsequent reviews, reviews of changes to safety related aspects of the facility or activity, reviews of operating experience, or reviews of long-term operation, life extension, decommissioning or release from regulatory control). The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
S8	**Suggestion: ARN should consider establishing provisions in its management system for application of a graded approach in review and assessment process.**

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The IRRS team was informed that ARN staff is capable to carry out review and assessment responsibilities independently; this is one of the key factors that support its effective regulatory independence. The staff competence is managed by line managers on the base of specific training by the Education and Training Unit (UCE), which was established under the "Regional Training Centre for Latin America and the Caribbean for Education and Training in Nuclear, Radiological, Transport and Waste Safety" in collaboration with the IAEA. The unit provides training to, *inter alia*, regulatory staff. In addition, ARN has an operational unit that fulfils the role of an internal TSO for radiation safety matters. Moreover, ARN has also a system to engage external TSO, for resolution of complex safety issues beyond the technical capacity of ARN staff, through a formal process of procurement of engineering, technical or consulting services. Apart from these arrangements, there are two Advisory Councils to the ARN´s Board of Directors which support the decision making during the licensing processes. The IRRS team was also informed about the use of various computer codes for performing audit safety analyses to support the review and assessment process.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The IRRS team observed that there is limited guidance available on the format and content of documents submitted by the applicants of nuclear installations. Prior to the mission, ARN also identified the need to develop guidance documents on format and content of licensing submissions for different types of nuclear installations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN has not developed comprehensive regulatory guidance on format and content of the documents submitted by the applicant in support of a license application for nuclear installations. For NPPs, the ARN's expectations regarding the format and content of these documents are specified in individual Memoranda of Understanding (MOU) that are signed between ARN and the applicants on a case-by-case basis.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24, para. 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization.*
S9	**Suggestion: ARN should consider issuing guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization for nuclear installations.**

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The IRRS team was informed that ARN performs different types of reviews and assessments of licensing documentation including safety reports, design documentation, safety assessments, models, and seismic studies, which comprise:

- Assessments to verify if procedures, general programmes and/or planning documents are according to the expected technical objectives;
- Reviews of technical documentation in order to verify if descriptions and analyses demonstrate compliance with safety requirements; and
- Assessments of modifications in the design of the facility or practice or the associated licensing base documentation.

In all cases, completeness and quality of a particular safety assessment is evaluated by the specialist(s) in- charge of performing the review and assessment, keeping in view the licensing stage and by applying a graded approach. Acceptance criteria are often taken from ARN and international standards. The review and assessment process is supplemented by on-site regulatory inspections (and vice-versa) which aim to verify that the licensees comply with the corresponding safety objectives. Inspections are carried over different activities, such as siting activities, quality assurance, manufacturing processes, and specific safety-related procedures (operations, maintenance, repetitive tests, functional assays, etc.). In addition, regulatory audits of the facility's organization and the management system documentation relevant to nuclear or radiological safety are also carried out by ARN. An annual regulatory audit programme has been scheduled to establish this process. The purpose of these audits is to verify if management systems from licensees are adequate, and also allow detecting if compliance with safety requirements is relaxed in certain areas or activities, which may trigger the need to carry regulatory inspections.

The IRRS team observed that although ARN performs review and assessment of operation of individual systems and areas of nuclear installations to augment the inspection findings, there is no formal process for performing integrated safety assessments, i.e. independent, systematic and comprehensive assessments by the regulatory body of the safety performance of a regulated facility. Integrated assessments are performed by reviewing outcome from all regulatory activities in an integrated manner enable the identification of trends and conclusions, including areas for improvement, and any necessary regulatory response.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN does not perform an integrated safety assessment for facilities and activities.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.46 states that** *"For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant…. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach".*
R8	**Recommendation: ARN should develop a formal process to perform integrated safety assessments, as referred in GSR Part 1 (Rev. 1), periodically by combining the results of review and assessment and inspection to identify trends and draw conclusions on safety of facilities and activities in a systematic manner, in accordance with graded approach.**

The IRRS team also observed that there is no mechanism to require the licensees to perform an independent verification of the safety assessment before it is submitted for review to ARN. The team was informed that in some cases (for NPP) the requirement is mentioned as a condition in the quality plans of the licensee. The IRRS team felt the need for ARN to include such requirement in the relevant regulations for different types of facilities and activities, in accordance with a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN does not require applicants to perform an independent verification of safety assessments before it is submitted to the regulatory body for review and assessment.*	
(1)	**BASIS: GSR Part 4 Requirement 21 states that** *"The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body."*
R9	**Recommendation: ARN should require applicants to perform an independent verification of safety assessments in accordance with a graded approach before submission to the regulatory body.**

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

The nuclear reactors licensing process is based on a stepwise approach. The first step is the submission of a Preliminary Safety Analysis Report (PSAR) and subsequent grant of Construction License by ARN following its approval. The authorization allows the licensee to start-up the civil works and is valid until the construction is completed. Once the process of assembling and the installation of systems, structures and components is being finalized, the facility may request the Commissioning License. During this stage, which could be subdivided into different phases, the objective is to ensure that every structure, equipment, system or component is in accordance with its design specification and that it can fulfil its intended function. The next milestone is the issuance of the Operating License, for which the Final Safety Analysis Report (FSAR) is required to be approved by ARN.

The review and assessment of the documentation submitted by the NPP is performed through carrying out different types of evaluations and inspections as per internal procedures of ARN. Reviews may result in the identification of the safety significant issues based on an in-depth analysis by applying the principles of graded approach.

The IRRS team was informed that ARN does not have a standard or guide that indicates what information should be included in a safety report. However, ARN agrees to a minimum content of this document with the licensee based on international standards which is used as a reference during the review and assessment process. ARN is in the process of developing a standard and the corresponding guide (see S7 in section 6.1.1). The team also observed that there is no specific procedure within ARN

management system documentation to address the application of graded approach which is usually determined by ARN on the basis of expert judgment. (S8 in Section 6.1.1 addresses this issue).

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

The general requirements for the authorization process of Research Reactors and critical assemblies are specified by ARN Standard AR 0.0.1. For each of the different licensing stages including construction, commissioning, operating and decommissioning the installation is required by ARN to submit mandatory documentation for review and assessment as per the requirements of the Standards AR 4.7.1, AR 4.7.2 and the licence issued for the corresponding stages by ARN.

During reactor operation, ARN receives routine and non-routine evaluation reports for review and assessment which are reviewed in accordance with the internal procedures P-CRNO-09 and P-CRNO-11 respectively. The review and assessment process is supplemented by the audit safety analysis performed by ARN using the analytical computer codes.

The IRRS team observed that the ARN regulatory framework for research reactors lacks specific standards for format and content guidance on preparation of a Safety Analysis Report (SAR), Probabilistic Safety Analysis, Deterministic Safety Analysis and conduct of a Periodic Safety Review. Currently the requirements for these are based on either internal documents or the conditions of the licence issued (see R15 in section 9.3). The IRRS team, however, acknowledged that the development of several regulations and regulatory guides for research reactors are part of the ARN action plan. (See 5.3. Authorization of Research Reactors).

ARN has formally enforced quantitative probabilistic safety criteria for the purpose of verifying the appropriateness of licensing the operation of nuclear reactors; such criteria are: (i) coherent and consistent with the international criteria for limiting risks attributable to ionizing radiation exposure; and (ii) sustained with application requirements established by formal regulations.

6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

The review and assessments for fuel cycle facilities is carried out in accordance with the internal ARN procedure P-SCICC-02. The procedure is used to carry out radiological and nuclear safety assessments in the licensing stages of fuel cycle facilities; as well as in the case of evaluations associated with the granting of authorizations for non-routine practices. The procedure contains distribution of ARN staff responsibilities within the assessment process and detailed sequence of related activities. Regulatory guidance has not been developed by ARN for prescribing the format and content of the documents to be submitted by the applicant in support of a licensing application for fuel cycle facilities (see S9 in section 6.1.3).

In accordance with licence conditions, licensees should send a 3-month-basis safety report on current nuclear and radiation performance and safeguards to ARN headquarters. In case of operating event occurrences, the licensee should inform ARN (in 24 hours) and send the event investigation report within 30-days timeframe. All these reports are analysed by staff of ARN responsible departments. If the information presented by the licensee requires further investigation or regulatory actions, the responsible ARN staff may arrange for an unplanned inspection, send a warning letter, or take other relevant measures accordingly.

6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The Standard AR 0.0.1, Licensing of Class I facilities, establishes that, prior to the application for a licence, the responsible entity shall submit to the regulatory authority the technical documentation necessary to evaluate the radiological and nuclear safety of the Class I installations, with the anticipation that it determines for its assessment.

ARN has a work instruction IRU-SPRIP-01 R 01, which guides staff in the review of the Safety Assessment Report for general radioactive waste management installations. This report, as well as other information required by the licence is evaluated by ARN. Facilities regulated by ARN, including those for radioactive waste management, shall renew their licences periodically after updating their safety assessment and relevant mandatory documentation.

The procedures P-SCIC G-02 “Evaluation of the radiological and nuclear safety for Class I facilities and fuel cycle facilities” and P-SCIC-01 G-03 “Inspections of the radiological and nuclear safety of Class I radioactive facilities and fuel cycle facilities” are used by ARN staff for performing the corresponding reviews and assessments of the documentation related to radioactive waste management activities.

The requirements established in the standards listed in section 9.5 are used as the applicable acceptance criteria during the review and assessment process.

6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The applicant has to prepare and submit to ARN a safety assessment that demonstrates compliance with all the regulatory requirements regarding radiological and nuclear safety, physical protection and safeguards. The scope and details of these documents are based on the classification of facilities and activities (installations and practices) following the criteria established, namely in the Basic Safety Standard (AR 10.1.1) and outlined on ARN’s website for several types of Class II and III practices.

ARN has issued guidance on the format and contents of the documents to be submitted by the applicant in support of an application for authorization for several Class II practices. This guidance covers gamma radiography, other industrial applications, nuclear medicine, radiotherapy, transport, import/export of sources. The guidance is available at the ARN web site.

The safety assessment that is prepared by the applicant and presented to the regulatory body must be carried out by a person with an individual licence issued by ARN.

The IRRS team observed that some practices and facilities, e.g. gamma radiography source storage facilities, the required information to be included in the safety assessment is focused on estimation of dose rates and doses at certain points of interest and does not address the radiation risks associated with normal operation, anticipated operational occurrences and accidents, including possible events with a very low probability of occurrence. For gamma radiography practices, the required content of the safety assessment available on ARN website includes:

- For the storage of radioactive material: detailed floor plan, indicating the relative location within the facility, dimensions, construction materials, uses of adjacent premises, occupancy factors and estimation of dose rates and doses at points of interest, in order to demonstrate compliance with dose limits in place;
- For an irradiation enclosure: detailed floor plan, indicating the relative location within the facility, dimensions, construction materials, uses of the adjacent premises, occupancy factors and estimation of dose rates at points of interest, in order to demonstrate compliance with dose limits in place, together with a description of the security systems of the premises.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *For some Class II practices, e.g. gamma radiography, the required information to be included in the safety assessment does not address the radiation risks associated with normal operation, anticipated operational occurrences and accidents, including possible events with a very low probability of occurrence.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 25, para. 4.33 states that** *“Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [9], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.”*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 26, para. 4.43 states that** *“The regulatory body shall assess the radiation risks associated with normal operation, anticipated operational occurrences and accidents, including possible events with a very low*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	probability of occurrence, prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable."
S10	**Suggestion: ARN should consider updating its regulatory guidance on the scope of the safety assessments for all Class II practices to ensure it considers normal operations, anticipated operational occurrences and accident conditions.**

Furthermore, by requiring the safety assessment to demonstrate compliance with dose limits, the regulations do not determine that the applicants should establish dose constraints for the practice. Optimization measures for protection of workers and the public are not addressed in this document (see R18 in section 9.9).

The safety assessment submitted by the applicant in an application is reviewed by ARN staff; any clarifications or corrections that are necessary are requested as part of this review. However, this is not based on a formal internal process. (See R5 in section 4.5).

The IRRS team observed through ARN's information management system for Class II and III practices, that staff has access to a list of pending results from inspections carried out on applicants, and take this information into account when reviewing the applications for authorizations.

Furthermore, for Class II practices, the IRRS team observed there are no provisions outlining situations where independent safety assessments may be required, taking into account a graded approach. (See R8 in section 6.1.4).

6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

The IRRS team observed that the content of the preliminary and final decommissioning plans of a facility is described in the ARN instruction SPRIP-01 R 01. The operating licences for Class I facilities specify when the responsible entity is required to submit the final decommissioning plan (typically between six and twelve months before the application for the licence of decommissioning of the facility), as well as that the operator must keep specific documentation, including the decommissioning plan, up to date. With every renewal of the operating licence, the responsible entity shall submit an updated preliminary decommissioning plan in accordance with a defined regime, as described in Section 5.7.

The IRRS team was informed that review and assessment during decommissioning is performed according to the generic procedure for assessment of application to all ARN technical units, considering the requirements established in AR 3.17.1 "Standard Decommissioning of Nuclear Reactors", and the instruction on the content of decommissioning plan as mentioned above.

ARN can initiate enforcement action in case of non-compliance with the national legal and regulatory framework, or with the licence conditions and safety requirements established by the regulatory body. During review and assessment of the decommissioning reports, ARN verifies the transfer of the radioactive material to the authorized destination, the adequate management of the radioactive waste generated during the decommissioning stage, the decontamination of surfaces, equipment etc., before issuing authorization for decommissioning.

6.8. REVIEW AND ASSESSMENT FOR TRANSPORT

The transport package/material approval process requires ARN to carry out assessments of technical and management systems relating to package/material design. The assessment process is managed by the two dedicated transport inspectors within ARN, technical specialist assessor capability is obtained either from within ARN or from external technical contractors. These specialists are given training on the requirements of the transport regulations by the ARN transport team.

Assessment of technical aspects cover the key areas of criticality, shielding and containment/thermal as required by SSR-6, the amount of assessment follows a graded approach. The management

arrangements of the applicant are assessed by the transport team who also carry out an inspection in accordance with defined instructions. The assessment activity is recorded by the specialists in a report format and provided to the transport team who then collate the recommendations and significant findings into a final report in a set format F-TMR-01. This report clearly identifies the decision to issue a certificate, the certificate is also produced at this time. The final report and certificate are subjected to review and approval process prior to the certificate being issued.

6.9. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

ARN has implemented procedures for assessing licensees' applications to ensure that they meet the requirements for protection of workers. This assessment includes the personal monitoring arrangements, information on workers involved, workplace monitoring plan and procedures for the operations that will be carried out. ARN also verifies the optimization process carried out for occupational exposure, and is able to request further optimization if needed during the assessment. Dose records are regularly requested and received from registrants and licensees as a condition stated in the authorizations.

6.10. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

Review and assessment is carried out at the design and licensing stages of the medical facilities, using the ARN Standards 8.2.1 to 8.2.4 as the bases for review and assessment. The licence issued to medical accelerator facility was presented to the IRRS team as an example during the interview. Operational license is issued by ARN based on the review of the design of the facility, equipment, qualified and trained manpower, availability of requisite instruments and the performance acceptance protocols of the equipment. For the renewal of licenses and authorizations, the performance of the installation is evaluated by reviewing the technical documentation, regulatory inspections results and any other appropriate evaluation, as well as compliance with current regulations and corresponding regulatory requirements issued by ARN.

The IRRS team observed that ARN does not have an internal guidance document for review and assessment (see S7 in section 6.1.1).

Assessment of justification of medical exposures is not performed by ARN. However, the licensee is required to justify medical exposures, as per Standard AR10.1.1. In addition, ARN has prepared draft "Guidelines for the implementation of the Management System for Safety in Medical Practices" to provide guidance to licensees on implementation of justification and optimization in Medical Exposures.

Regulatory Standard 10.1.1- Rev 4 requires that the responsible entity shall develop and implement an adequate management system. The IRRS team was informed that ARN does not have competence in health issues, so the verifications are only limited to the radiological safety management systems associated with medical practices. ARN Standards for radiotherapy require the physicist to implement the quality programme, that comprises the quality of the medical exposure, and to carry out the dosimetry calculations of the patients. For case of Nuclear Medicine practice, the Standards require implementation of a Quality System and the Responsible Entity as well as the person responsible for radiological safety must include in this Quality System the protocols that they will follow to carry out the procedures at the facility. However, for issuance of licence for nuclear medicine practice, the review of QA tests is limited to calibrations of the isotope calibrator and other monitoring instruments and QA of the imaging equipment is not included in the review and assessment procedure for issuance of license. The IRRS team also observed that ARN does not require the licensees for carrying out periodic radiological review of the facilities (see R19 in section 9.10).

6.11. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

ARN requires the submission of, and reviews, the safety assessments and other design related documents before authorization of a new or modified practice including the assessment of exposure and potential exposure of members of the public.

The Responsible Entities shall demonstrate compliance with ARN Standards and requirements through safety reports, procedures, instructions, manuals, environmental radiological monitoring programs in

compliance with the corresponding license. ARN evaluates the documentation submitted by all facilities during the different stages of their life. In Class I installations, safety reports, submitted by operators at the time of applying for a licence, contain a section on environmental impact and dose to the public.

In the design stage of an installation, prospective doses are calculated by models in the representative person, due to the discharge of radioactive effluents. During the operation of the facilities, ARN calculates the retrospective doses to the real representative person for each facility.

Regarding the control of radioactive effluents and radiological environmental impact assessment, ARN performs the following tasks:

- Evaluates the information provided by the operator (expected radionuclides in the different discharge routes, their activity concentration, their impact, etc.) at the design stage of the installation;
- Determines the authorized discharges values for each installation;
- Evaluates discharges of radioactive effluents reported by operators periodically, in compliance with the operating license of each installation;
- Keeps records of gaseous and liquid discharges of all Class I installations;
- Calculates, from the reported discharges, the doses in the public (representative person);
- Evaluates the environmental radiological monitoring programs presented by the operator and verifies the levels of radionuclides in the environment associated with the relevant facilities, ARN has its own environmental monitoring programme to perform an independent verification. The determinations made in this regard are carried out in ARN´s own laboratories;
- Verifies for nuclear power plants the control that the operator exerts on discharges, by evaluating the procedures for sampling discharges and their measurements (including measurement systems, equipment calibration, calculations for determinations and calculations of uncertainties) of them by the operator, as well as the performance of intercomparisons on the determination of some radionuclides and sampling campaigns in parallel with the operator.

For medical facilities (Class II - radiotherapy and nuclear medicine), the calculation reports include the calculation of doses in public use enclosures that border on the irradiation bunkers and/or hot rooms, as appropriate. Additionally, rehabilitation inspections include dose rate measurements in these premises for the purpose of confirming that the exposure values are consistent with the values declared in the calculation reports and that they comply with the dose restrictions established for the public.

The remediations of mines in Argentina were originated from planned exposure situations, thus it is considered as an activity regulated by ARN. The entire remediation process until the final release of the site will be reviewed, inspected and authorized by ARN. The doses and restrictions associated with this process will be those established in Standards 10.1.1 and 2.12.1 (in case of the mining sites).

6.12. SUMMARY

The review and assessment process of ARN is quite comprehensive according to the national standards, however, several gaps were identified by the IRRS team in conformance with the IAEA safety standards for further improvement of its regulatory framework and management system including the following:

- need for developing internal guidance for ARN staff to perform the process in a more standardized and effective manner;
- prescribing a methodology for application of graded approach in review and assessment in the management system;
- developing guidance for the licensees on format and content of documents submitted for review by the regulatory body in support of the licence applications for nuclear installations;

- developing a formal process to perform periodically integrated safety assessment to assess the overall performance of a facility by combining the results of review and assessment and inspection to identify trends and draw conclusions on safety of facilities and activities:
- incorporating more transparency and accuracy in the safety assessment of the facilities and activities by requiring the licensees to perform an independent verification of safety assessment before submitting it to the regulatory body for review and assessment.

7. INSPECTION

7.1. GENERIC ISSUES

ARN has established a systematic approach for conducting inspections that is in accordance with the requirements of the IAEA safety standards. Specifically, ARN has produced several inspection procedures which define the frequencies for inspections. Procedures also provide guidance on how to conduct inspections. The inspection procedures cover all areas of ARNs regulatory oversight. Examples include:

- P-CRNO-02 R2: Routine Regulatory Inspections to NPPs During Power Operation;
- P-CRNO-03 R2: Planning and Execution of Regulatory Inspections for Programmed Outages in Nuclear Power Plants;
- P-LCRN-02 R00: Regulatory Inspections to Grant the Commissioning License;
- P-LCRN-03 R00: Regulatory Inspections to Grant Operating License;
- G-1XX-13 (Rev 2): Inspection to Radioactive Source Transfers (Cobalt Therapy);
- P-CRNO-06 (Rev 2): Inspection and Technical Audits to Research Reactors and Critical Assemblies;
- P-CLASE I-01 (Rev 2): Nuclear and Radiological Safety Inspections to Radioactive Class I Facilities and Fuel Cycle Facilities;
- P-Class II-11 (Rev 3): Inspection to Class II Facilities;
- I-PRIP-02 Radioprotection Inspection Plan for Nuclear Power Plants During Outages;
- P-SPRIP-06: Radioactive Waste Management Inspection for NPPs.

ARN inspectors are guaranteed unrestricted access to facilities and activities under ARN regulatory control, without prior notification, through ARN Resolution N° 004/2000, dated on 04/01/2000 titled "Regime for the Access of Inspectors to Installations under (or subject to) Control of ARN". This Resolution is included as a licence condition for each licence.

Inspection methods applied by ARN include examination and evaluation of procedures, records and documentation, surveillance and interviewing of personnel. Additionally, inspectors have the authority to take samples and perform measurements if required. The results of ARN's inspections are rated according to their safety significance and documented in inspection reports.

At the time of the IRRS mission, the ARN did not have a documented and approved inspector training or qualification programme. Inspectors do receive technical training in many areas and on-the-job training is also provided, however, a systematic or approved training and qualification process has not been developed. Additionally, ARN does not formally designate inspectors, as such, it is not clear who may exercise the powers of an inspector. The inspector profiles are identified by the Human Resources department for each area or type of installation, and each inspector is allocated to the position according to its qualifications, and subject to performance assessment periodically by the immediate supervisor.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN has not established an inspector training and qualification programme to ensure that inspectors develop and maintain the competency necessary to perform their duties.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 2.34 states that** *"As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSG-13 para. 3.312 states that** *"The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions, which should be documented in internal guidance. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures."*
R10	**Recommendation: ARN should further systematize the training and qualification of inspectors to ensure that all inspectors possess all the necessary competence to perform their duties.**

7.2. INSPECTION OF NUCLEAR POWER PLANTS

ARN has established a comprehensive inspection and oversight programme to verify compliance with regulatory requirements and licence conditions established for Nuclear Power Plants (NPP). At the time of the IRRS mission, there were three operating NPPs in Argentina: one at the Embalse site and two units at the Atucha site. Resident inspectors are present at each of the NPP sites, typically there are two inspectors and a coordinator at each NPP. The resident inspectors are supported by inspectors from the Division of Engineering, Division of Radiation Protection and Division of Safeguards Control and Security to ensure all required competencies are available. In total there are approximately 20 inspectors who support the oversight of NPPs. The planning, execution, reporting and follow up activities of inspections are guided by the ARN management system and described in the inspection procedures identified in section 7.1.

For NPPs, ARN has established routine and non-routine inspections, which can be conducted announced or unannounced. Routine inspections are conducted during normal operation and outages. Routine inspections are also conducted for the review of scheduled licensee submissions on performance indicators and other reports. Non-routine inspections are conducted when changes are made to safety significant systems, structures, components, and documentation as identified in the licence. Additionally, non-routine inspections may be initiated because of events or non-compliances by the licensee. Inspection results are documented in inspection reports. Areas requiring follow-up are identified for the licensee to provide clarification or take corrective action. For most inspections, inspectors are provided with detailed work instructions and checklists to ensure inspection activities are conducted thoroughly and consistently. Inspectors follow a formal process for documenting recommendations for further review. These recommendations are reviewed by the ARN management and may result in changes to the work plan.

An annual inspection plan is generated and approved each year for each NPP, as required by ARN procedure P-CRNO-02 "Routine Regulatory Inspections at Nuclear Power Plants in Operation". The template for the annual plan (F-UGC-02) identifies the mandatory inspections which must be completed. Flexibility is provided to the inspectors in the selection of individual tasks to be inspected using their professional judgement, results of previous inspections and the performance of the facility. The inspections carried out during outages of the nuclear power plants use a flexible planning process since the activities performed vary from outage to outage. ARN requires licensees to submit outage work plans 60 days in advance of the outage so that inspections can be planned, and appropriate resources can be assigned to conduct the work.

Resident inspectors receive training in many technical areas including radiation protection, reactor technology and NPP systems. In addition, resident inspectors shadow licensee operations staff for one month when they begin as an inspector, to gain familiarity with the NPP. A draft inspector training and qualification programme has been prepared by ARN staff, however, since this programme has not yet been approved or implemented, as such, the IRRS team made a recommendation in section 7.1 on the topic of inspector training. When required, resident inspectors do participate in inspections at other NPP facilities. This being seen as a good opportunity to share knowledge among inspectors and ensure consistency in the conduct of inspections. These inspector exchanges are not formalized and only occur in situations when additional support is required due to workload. As such, the benefits of the exchanges

could be lost if workload does not require support from visiting inspectors. The IRRS team encourage inspector exchanges to be included in the inspector training regime to ensure that the practice continues.

The IRRS team observed an onsite inspection of routine tests conducted by NPP staff. Specifically, the team observed the starting and testing of a diesel generator at the Embalse NPP and were accompanied by ARN counterparts. The ARN inspection team consisted of two Embalse ARN resident inspectors who were familiar with ARN work instructions and inspection procedures. They presented the approved 2022 inspection plan to the IRRS team for review. The inspection was executed using the approved work instruction (IDT-CCNO-02) and its associated checklist, as well as the procedures used by licensee staff. Inspection results were documented and discussed with licensee staff including areas for follow up and requests for clarification. In the opinion of the IRRS team, the ARN resident inspectors were professional, knowledgeable, and well prepared to conduct the inspection. In their preparation, the inspectors specifically discussed health and safety concerns as well as specific items which had been identified in previous inspections. The IRRS team also met the Embalse NPP Manager, who identified that the work of ARN provides valuable feedback on the performance of the facility and adds value. The manager spoke of observations and findings which had been made by the ARN inspectors and was familiar with regulatory requirements as well as possible sanctions which could be enforced for non-compliances.

Design modifications of existing nuclear power plants may require authorization from the regulatory body before being implemented, depending on their safety significance. NA-SA has established a procedure to categorize design modifications in NPPs according to their safety significance, following a graded approach (implementation of Category A modifications must be authorized by ARN). The IRRS team noted that the implementation of this procedure is inspected by ARN inspectors.

7.3. INSPECTION OF RESEARCH REACTORS

There are five research reactors (RR) of various designs in Argentina, three in nuclear research centres and two in public universities. Inspections of research reactors are carried out in accordance with the internal ARN procedures. ARN have a range of inspection types and techniques specific for RRs defined in their procedures (e.g., inspection of experimental equipment or isotope production). Inspectors use a selection of methods during inspections: document reviews, interviews, site-visits and observation of activities. The inspection is recorded via a check list detailing findings, equipment and radioactive source inspected. The output of the inspection is presented to the reactor manager. A formal report is written after the inspection which details any formal findings which ARN sends to the licensee. There is an annual inspection programme, which is updated as needed, including either 3 or 6 inspections per research reactor depending on power level. ARN inspectors are also empowered to carry out reactive inspections as required by facility performance. The IRRS team noted that the inspection plan was not fully implemented during the pandemic.

Inspectors involved in research reactor inspections are all technical specialist with many years of experience. In addition to technical studies, they have completed a one-year course in nuclear safety and radiological protection. Some inspectors have also participated in on-the-job training in other countries.

The IRRS mission accompanied a standard inspection of the research reactor RA-1. ARN inspectors formed a team consisting of three specialist inspectors in nuclear engineering and radiological protection. The scope of the inspection was radiological protection and protective action. The inspectors had free access to the reactor site and the interactions between inspectors and the licensee were professional. Inspectors first met with the reactor manager to discuss the scope of the inspection. Then, they carried out a review of documents with the radiological officer. The inspectors took measurements of radioactive isotopes in the reactor cooling system, resin and the reactor building. Inspectors also took samples of cooling water which were taken to be tested in the ARN laboratories. Inspectors concluded with a review of progress against corrective actions identified from previous inspections. It was a routine inspection and the experienced inspectors carried it out smoothly according to the schedule. No non-compliances with the applicable requirements of the IAEA SSR 3 standard were found.

7.4. INSPECTION OF FUEL CYCLE FACILITIES

An annual inspection plan is developed every year by ARN staff. It identifies the frequency and scope of inspections for each facility, considering its classification, existing hazards, compliance history and scale of operation. Usually, for Class I fuel cycle facilities, ARN perform up to four inspections per year. For Class II facilities, the average number of inspections is 1 per year. For Class III facilities, ARN staff perform 1 inspection every two years. In addition, reactive inspections may be initiated if required. Inspections are conducted by ARN inspection teams consisting of 2 or 3 inspectors. The total amount of licensed fuel cycle facilities is as follows:

- Class I fuel cycle facilities: 16;
- Class II facilities: 23; and
- Class III facilities: 4.

Inspectors are provided with a work instruction to ensure inspections are conducted consistently. ARN procedure P-SCICC-01 Rev. 3 "Inspections of Radiological and Nuclear Safety to Class I Radioactive Installations and the Nuclear Fuel Cycle Facilities" describes the methodology of inspections.

The IRRS team observed an ARN planned routine inspection conducted at the ECRI Facility, operated by CNEA. ECRI is a fuel fabrication facility producing nuclear fuel bundles and targets for Argentina research reactors RA-3, RA-10, as well as for similar research reactors abroad. Inspectors inspected radiological safety conditions of the facility, made in-field dose rate measurements, reviewed enriched nuclear material storage conditions, and verified the implementation of relevant facility procedures and compliance of the previous inspection requirement that shall be fulfilled by the facility. During the inspection, the IRRS team identified compliance with the relevant IAEA guidelines on regulatory inspection of nuclear facilities.

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

The IRRS team was informed that every year, an annual inspection plan is established in accordance with a graded approach as follows:

- Class I facilities, an inspection is performed quarterly;
- Class II facilities, an inspection is performed annually;
- Class III facilities, an inspection is performed every two years.

The IRRS team was informed that there are non-routine inspections (planned or not) to verify specific aspects of the activities carried out at the installation. For radioactive waste facilities, inspectors are provided with the following regulatory documents to ensure inspections are conducted consistently:

- Procedure P-SPRIP-06 "Inspections of radioactive waste management in NPP";
- Regulatory guide A 13 "Storage of radioactive waste";
- Regulatory Standard AR 10.12.1 "Radioactive waste management".

Routine inspections consist of document reviews and visiting on-site areas of interest with the aim to verify compliance with safety assessment and regulatory requirements. Inspection results are reported in a specific form to the corresponding ARN department and then to the licensee. Based on the relevance of the findings, these are discussed with managers of the facility, establishing actions to follow up and deadlines for compliance with requirements. ARN inspector's follow-up on findings is carried out through the evaluation of licensee documentation and subsequent inspections. The results of inspections feed back into the verification process of compliance with the requirements established by ARN.

The IRRS team observed an inspection performed at the radioactive waste interim deposits at the Atucha NPP site. The objective of the inspection was to confirm that radioactive waste drums were transferred from the DATRRII deposit to the DATRRIII deposit and that all required checks and measurements were completed. The IRRS team deemed that the ARN inspection was conducted in a very professional,

transparent, and constructive manner. The inspection had been carefully prepared in accordance with the applicable ARN procedures, and a comprehensive checklist had been completed. The inspection was attended by the radioactive waste management responsible of Atucha site licensee (NA-SA).

The inspection plan had been communicated to NA-SA in advance of the inspection and consisted of the following parts:

- Entrance meeting, where the ARN inspectors summarized the process of movement of radioactive waste drums from deposit DATRRII to deposit DATRRIII, and the objective and scope of the inspection;
- Document review, where a follow-up of the activities performed by the licensee since the previous inspection was performed, as well as the revision of the corresponding supportive documentation;
- Interim deposits tour, where a visual inspection on the deposits state was done. Dose rate measurements and smear sampling were carried out at selected locations. The equipment for dose rate measurements and the smear filters were property of ARN; and
- Exit meeting, where the results of the inspection were exposed by the inspectors. They explained that the inspection results were positive, and that there were no findings.

Following the inspection, the IRRS team held a separate meeting with the person responsible for radioactive waste and the management staff at Atucha NPP. These representatives confirmed that interactions with ARN is open, efficient, and constructive. They indicated that the regulatory body is transparent, and inspectors clearly communicate inspection results including areas for improvement.

7.6. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

For Radiation Sources Facilities and Activities, inspections carried out by ARN to verify that facilities are operated in accordance with regulatory requirements and the conditions established in the licence. In this area, ARN has a team consisting of three inspectors specializing in accelerators, four inspectors specializing in radioactive facilities, four inspectors specializing in gamma radiography, four inspectors specializing in other industrial applications, five inspectors specializing in radiotherapy, five inspectors specializing in nuclear medicine. Inspectors have university education in the relevant areas.

In general, the inspection procedures apply a graded approach that include control of systems and components important to safety, appropriate radiation monitoring, records auditing of internal control results, compliance with operational procedures, the management system, and the behaviour of workers in relation to operational radiation protection procedures (safety culture, housekeeping, and compliance with codes of practices and good practices in general).

For Class I facilities inspections are carried out at least twice a year. For some source manufacturing activities, four inspections per year are carried out. For Class II and III facilities, an inspection programme is followed taking into account a graded approach. Reactive inspections are carried out whenever necessary. Non-compliances found from the regulatory inspections can trigger corrective actions or penalties to the licensee, as appropriate. The results of the inspections are recorded in an inspection report that is signed by the ARN inspectors jointly with the corresponding representative of the authorized party. Results of inspections are recorded in ARN's information management system for Class II and III practices (SIRFRAR), along with the report and identified non-compliances and deadlines for correction. Follow-up inspections are prepared taking into account the information collected from previous inspections and involve verification of the implementation of corrective measures that are pending.

The IRRS team observed that the information management system for Class II and III practices (SIRFRAR) allows for ARN inspectors to receive reminders of non-compliances that are pending resolution from the authorized parties, facilitating the regulatory oversight activities and planning of follow-up inspections.

ARN and the Ministry of Health share responsibilities in regulatory control of medical exposures. The IRRS team was informed that joint inspections were not carried out for facilities and activities where multiple authorities have joint regulatory oversight, e.g., PET/CT facilities, that involve x-ray generators and radioactive materials. It was further noted that when conducting inspections on practices regulated by ARN involving medical exposures (e.g. nuclear medicine and radiotherapy), inspectors have limited access to information considered as health data (e.g. concerning patient data). This highlights the need for collaboration between the involved authorities (see R1 in section 1.5).

The IRRS team observed an ARN inspector team that carried out a planned, announced inspection to Dioxitek, operator of a radioactive source manufacturing facility. The ARN inspectors conducted the inspection in a very professional manner. The inspection was carried out according to pre-established procedures and checklists, demonstrating a very good preparation. The inspection started with an entrance meeting, where the objectives were clearly communicated, both orally and in written documents that were prepared in advance and were distributed to the operator. This documentation outlined the scope of the inspection and the checks to be carried out. The inspection involved a review of pending actions from previous inspections, through the review of safety-related records. During the walk-down in the facility, the inspectors carried out independent verification measurements and tests of safety systems. They also conducted visual verification of the serial numbers of sources stored at the facility, namely in the storage pool. These serial numbers were compared to the inventory of the facility, in order to confirm the correctness of the information (source ID, storage location).

At the end of the inspection, a report was prepared by the inspectors, outlining new pending actions for the next inspection. The report was prepared in duplicate form, reviewed, and signed both by representatives from the facility and the inspectors. The IRRS team met, in a separate interview conducted at the end of the inspection, the operator representatives. They described the relationship with ARN as very good and is established on a mutual trust between both parties. It was highlighted that the availability of ARN personnel to clarify questions directly was a good way to enhance the official communication channels. It was added that the existing regulations and guides (in this case, for Class I practices) were very clear and transparent.

In contrast, the operator mentioned that some regulatory processes of ARN, e.g. obtaining personal licenses for facility staff, can be very slow, and this sometimes creates difficulties for its activities.

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

Inspection plans regarding decommissioning activities are developed on the basis of the final decommissioning plan. The IRRS team was informed that there are non-routine inspections to verify specific aspects of the activities carried out at facilities under decommissioning. For decommissioning activities, inspectors are provided the following work instructions to ensure inspections are conducted consistently:

- P-SRIP-04 PRIP “Management of safety evaluations in the Division of Radiological Protection in Facilities and Practices”;
- P-SRIP-06 “Radioactive waste management inspections in NPP”;
- I-SRIP-02 “Radioprotection inspection plan for NPP”;
- F-SRIP-02 “Radioprotection inspection programme for NPP”.

Decommissioning inspections consist of document reviews and visiting on-site areas of interest with the aim to verify compliance with safety assessment and regulatory requirements. The resources to carry out any inspections are identified in the annual work plan. The results of decommissioning inspections are reported in a specific form (F-SRIP-04 Division PRIP report) to the corresponding ARN department/division and then to the licensee.

Based on the relevance of the findings, ARN inspectors discuss with managers of the facility, establishing actions for follow up and deadlines for compliance with requirements. The follow-up of the

findings is done through the evaluation of documentation presented in compliance with the license, and from information of other documentation and inspections.

There are four inspectors trained to carry out inspection related to decommissioning of NPP and research reactors (two of them are also involved in inspections on radioactive waste management activities), and other inspectors are dedicated specifically to other installations, covering all safety aspects.

The IRRS team was informed that a linear accelerator is currently under decommissioning. This facility is inspected twice a year, and the inspections cover all the safety aspects of its decommissioning

7.8. INSPECTION OF TRANSPORT

One of ARN's responsibilities under Act No 24.804 Article 16 d) is inspection of transport of radioactive material by all modes of transport within Argentina. ARN establishes annual inspection programme related to transport. The inspections cover both compliance assurance and are in support of transport package approval. ARN currently have two inspectors (reduced from 4 historically) to carry out inspections and approval activity. They are both experienced and have had suitable training primarily via on-the job experience. The staffing level has led to a small reduction in inspections carried out, reduced priority for standards updates and does not provide resilience to manage departure of staff (See R3 in section 3.3).

ARN plans approximately 30-40 planned compliance inspections of consignors annually. The number of inspections and which types of facility are to be inspected are planned at a high level in accordance with a documented instruction (I-TMR-04) and procedure (P-TMR-02). The specific selection of facilities for inspection is based on a graded approach, but this process is not documented.

Transport of radioactive material by land is inspected under requirements imposed by AR 10.16.1. Air and sea transport are regulated against the relevant UN modal texts (ICAO and IMDG). Driver competence is checked via inspection of licence issued by Ministry of Transport. Vehicles are inspected for aspects of AR 10.16.1 such as securing of loads, but other aspects of vehicle safety are not within ARN scope for inspection.

Compliance inspections are recorded in a document at the time of inspection (F-TMR-02), this is agreed with the licensee and a copy is provided to them at the time of inspection. The inspection is written up in a more formal record after the inspection using a different form (F-TMR-03). The outcome of inspections is generally well documented and contains the relevant information related to any non-compliances and agreed approach for returning to compliance. However, the scope and objectives of transport compliance inspections are not formally defined by ARN, either for use by inspectors or for provision to licensees. Inspections relating to approvals, first use of packages and package/material testing, all have suitable instructions.

The majority of compliance inspections are carried out unannounced and due to the size of the country tend to occur in blocks of time on a regional basis. Inspections relating to package approvals/first use are announced and planned with the licensee in advance. ARN has carried out inspections of vehicles during transport, whilst vehicle is stopped overnight or rest periods, but this is not a regular occurrence.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN does not formally document the scope or objectives of a transport compliance inspection, the scope and objectives are also not provided to organisations in advance.*	
(1)	**BASIS: SSG-26 Para 307.5 states that** *"A compliance assurance programme can only be implemented if its scope and objectives are conveyed to all parties involved in the transport of radioactive material (i.e. designers, manufacturers, consignors, carriers). Therefore, compliance assurance programmes should include provision for information dissemination."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S11	**Suggestion: ARN should consider documenting the scope and objectives of a transport compliance inspection and convey this information to all parties involved in the transport of radioactive material.**
Observation: *The method of determining the graded approach to transport inspections is not documented in a formal process.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 29, para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 22, Para 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body…"*
R11	**Recommendation: ARN should formalise the methodology by which transport inspection plans are developed in accordance with a graded approach.**

7.9. INSPECTION OF OCCUPATIONAL EXPOSURE

ARN has established an inspection programme for occupational exposures, the programme includes work instructions and guides for planning, conducting and reporting on inspections. The IRRS team noted that ARN has not implemented, through inspection, mechanisms for verifying the implementation of the workers' health surveillance programme for all facilities, as required by the Basic Radiation Safety Standard AR-10.1.1.

ARN has established some provisions for verifying psycho-physical aptitude of workers who are required to obtain or to renew individual licenses or permits. ARN does not specifically verify the implementation of the health surveillance programme (initial and permanent) during the inspections carried out at the facilities.

ARN has identified the need for additional measures, including adding checks during inspections, for improving the regulatory control and verification of arrangements implemented by licensees and employers for workers' health surveillance. Where an organisation is responsible for a source and external workers may be occupationally exposed to this source, licensees must make special arrangements for workers' health surveillance with the employer.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN does not verify the implementation of the workers' health surveillance programme for all facilities. There are no appropriate internal procedures in place for verifying the special arrangements needed among employers, registrants, and licensees, for the workers' health surveillance before the engagement of such workers.*	
(1)	**BASIS: GSR Part 1(Rev. 1) Requirement 27 states that** *"The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 3 para. 3.108 (b) states that** *"Programmes for workers' health surveillance as required in para. 3.76(f):* *(b) Shall be designed to assess the initial fitness and continuing fitness of workers for their intended tasks."*
(3)	**BASIS: GSR Part 3 para. 3.109 states that** *"If one or more workers are to be engaged in work in which they are or could be exposed to radiation from a source that is not under the control of their employer, the registrant or licensee responsible for the source shall, as a precondition for the engagement of such workers, make with the employer any special arrangements for workers' health surveillance that are needed to comply with the rules established by the regulatory body or other relevant authority."*
S12	**Suggestion: ARN should consider verifying in all facilities the implementation of the workers' health surveillance programmes, and when required, of special arrangements.**

7.10. INSPECTION OF MEDICAL EXPOSURE

ARN has five inspectors for radiotherapy and five for Nuclear Medicine facilities. The frequency of inspections for Nuclear Medicine and Brachytherapy facilities is once every two years and annually for teletherapy facilities. The inspections are mostly planned (routine). However, there are also provisions for unannounced inspections and reactive (non-routine) inspections. In 2022, 270 inspections are planned for medical facilities. ARN also carries out inspections as a part of the authorization process, especially prior to issuance of licence for medical facilities.

The routine inspections are carried out by ARN in accordance with inspection procedure P-Class II-11 (Rev 3): Inspection to Class II Facilities. During the preparation of the inspections to medical facilities there is a review of the mandatory documents and appropriate check lists for different type of equipment are defined. Generally, the check list includes items to verify the compliance with regulatory standards, inventory and calibrations records of radioactive sources and equipment, occupational dosimetry and operational records. Inspectors also check that preventive and corrective controls required and established in the Safety Management Systems, and that the operating parameters remain within the accepted limits (beam dosimetry, beam characteristics, calibrations of dosimeters and radioactive sources). In Nuclear Medicine facilities, stability in the response of the dose calibrator is verified. The Inspection reports are issued in accordance with Procedure P-CLASS II & III-10; Rev 3 "Issuance of notifications and generic recommendations to users operating facilities Class II and III", and are followed up by ARN to enforce the licensee to take corrective actions.

The verification of patient specific quality assurance in radiotherapy, patient dosimetry records and records for nuclear medicine equipment are not part of the inspection. The IRRS team was informed that there is a law under the jurisdiction of the health authorities that prevents access to the medical records of patients (Act N° 26.529), and it is thus not possible for the ARN to have access to patient dosimetry (see R1 in section 1.5). Moreover, ARN does not carry out verifications of arrangement for release of patients undergoing therapeutic procedures (Nuclear medicine and permanent implants). In nuclear medicine, it is not mandatory to hospitalize patients after procedures, patients are released based on their health. There are no dose restrictions established for their release (see R19 in section 9.10).

A site visit was conducted at radiotherapy institute Mevaterapia - Oncología Radiante, Buenos Aires. The institution operates four linear accelerators and one brachytherapy unit. The scope of the inspection was limited to one linear accelerator and one Co-60 High Dose Rate brachytherapy equipment. The inspection started an entrance meeting where the scope was explained to the licensee. The inspectors verified the individual permits, personnel dose records, quality assurance tests, equipment calibration records, compliance with findings from previous inspection, independent audit of the linear accelerator calibrations etc. as per the inspection checklist. It was observed that the inspectors had access to all

previous licensing and inspection records of the institution onsite through the SIRFRAR database of ARN. The documentation checks were followed by a walkthrough of the facility and the performance of mechanical tests of the linear accelerator by the inspectors to verify the accuracy radiation fields used for treatment. For the HDR equipment, the leakage radiation and the safety interlocks were checked. An exit meeting was held at the end of the inspection where the inspector informed the licensee about the compliance with applicable requirements and issued a copy of the inspection report.

The IRRS team interacted with the licensee about the regulatory relations, transparency and predictability of regulatory requirements and timelines for approvals. The licensee informed that the regulatory requirements with regard to medical exposures were clear and that additional requirements, if any, are communicated through notes by the ARN in advance. The ARN inspectors were also informed to be approachable and ready to provide any additional guidance through informal communication means.

7.11. INSPECTION OF PUBLIC EXPOSURE

Verification of compliance with the regulatory requirements for protection of the public is carried out through regulatory inspections for each type of practice or installation and following the assessment of the information provided by Responsible Entities to the regulatory body.

The inspections are carried out in accordance with a graded approach as well as the doses to the public in normal operation and potential exposures. During regulatory inspections, compliance with safety requirements, with the conditions specified in the authorization, and requirements for optimization, with the procedures and operational work instructions, with technical aspects related to protection of the public, are verified.

7.12. SUMMARY

The IRRS team considered that the inspection process as described in the ARN management system is being followed for nuclear facilities, transport, and the protection of exposed workers, the public and the environment during the use of radioactive materials. Inspections are conducted in a systematic and predictable manner; results are communicated to licensees and follow up of non-compliances occurs. Inspectors have unrestricted access to areas under regulatory control of the ARN and inspectors conduct both announced and unannounced inspections. The IRRS team conducted several observations of inspections at licensed facilities. The IRRS team noted that all inspections were conducted in an open and professional manner.

The IRRS team encourages ARN to systematize the training and qualification of inspectors to ensure that all inspectors possess all the necessary competence to perform their duties.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

Based on article 16 g) of the Nuclear Act, ARN has the ability to apply sanctions, which shall be graded according to the severity of the infringement. These include enforcement actions such as warnings, fines to be applied according to the severity of the non-compliance and the potential harm, suspension of a licence, permit or authorization or their revocation. Based on article 16 h) of this law, ARN has the power to establish procedures for the application of sanctions corresponding to the violation of regulatory standards issued while exercising its competence. Article 16 i) of the Nuclear Act gives ARN the power to provide for the seizure of nuclear or radioactive materials, as well as the preventive closure of installations subject to regulations of the ARN under defined conditions.

The ARN has a sanction regime, established according to a graded approach, for:

- Nuclear power plants (Resolution N° 63/99);
- Failure to comply with radiological and nuclear safety regulations, physical protection, safeguards and non-proliferation of nuclear in relevant installations (Resolution N ° 24 (11/11/99); and
- Facilities classes II and III, non-routine practices and transport of radioactive materials (Resolution N° 32 (26/8/02).

The IRRS team concluded that ARN has not established a comprehensive enforcement policy covering the whole range of enforcement actions. ARN deals with non-compliances under the threshold of the sanction regime verbally, with a written note or with imposing additional regulatory requirements as a means of enforcement. The procedure on inspection includes some provisions for non-compliances under the threshold of the sanction regime, such as who is in charge to take enforcement decisions. However, there are no written and specific criteria for determining the appropriate enforcement response.

The authorized party has the right to appeal a sanction at the National Administrative Contentious Court of Appeals. Until the court decides otherwise, the sanction continues to be imposed.

ARN has the power to promote civil or criminal lawsuits in the relevant courts when licensees or authorization or permit holders do not comply with the National Law of Nuclear Activity. In case of a possible criminal , the inspector will consult the legal department of ARN. The legal department decides if the information needs to be shared with the department of Justice.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The legal framework provides a sanction regime and ARN has established elements of an enforcement policy. However, ARN has not explicitly established a comprehensive enforcement policy for responding to all types of non-compliances according to a graded approach.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 30 states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization."*
(2)	**BASIS: GSR Part 1 (Rev. 1) para. 4.55 states that** *"Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance."*
R12	**Recommendation: ARN should bring the whole range of the possible enforcement actions under a comprehensive enforcement policy for responding to all types of non-**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	compliances according to a graded approach.

8.2. ENFORCEMENT IMPLEMENTATIONS

The majority of enforcement actions of ARN consist mainly of verbal notifications, written notifications and the imposition of additional regulatory requirements. ARN applies the sanction regime only in case of severe violations, resistance or non-compliance with the corrective actions by the authorized party. The IRRS team was informed that, since 2010, there have been three warnings and one fine imposed by ARN to NPPs.

Resolution ARN N° 159/22 contains the internal procedure for applying sanctions and the criteria for the application of fines. In case of a possible non-compliance an investigating officer compiles an investigation file. The ARN Board of Directors decides whether to continue with the proceedings. In case of continuation, the authorized party may offer a defence against the alleged infringement and offer any evidence they deem appropriate. Based on all this information, a final report is drafted. The legal service issues a legal opinion and submits the proceedings to the ARN Board of Directors. The ARN Board of Directors issues the corresponding administrative act in which it shall rule on the non-compliance and the sanction. The amount of the fine is determined according to the potential level of harm and the severity of the infringement.

All administrative decisions taken by the Board of Directors, including sanction decisions, have to be published in the national public gazette.

IAEA guidance on enforcement suggests that imposing penalties on the licensee rather than on individual workers is preferable as it is more likely to lead to improved safety performance, ARN can do both.

The inspectors of ARN have the power to take precautionary measures in the scope of their competence, with the urgency each situation requires, to protect people against the harmful effects of ionizing radiations or to mitigate such effects based on Resolution No 4/00.

ARN has not established an inspector training programme which includes enforcement policy and procedures (see R10 in section 7.1). ARN keeps records of the imposed sanctions and regulatory requirements.

ARN has identified the need to update the process for reviewing fines in order to cope with inflation more frequently.

8.3. SUMMARY

The legal framework provides enforcement powers to ARN. There is a sanction regime with a graded approach in place; however, there is no comprehensive enforcement policy covering the whole range of possible enforcement actions for responding to all types of non-compliances according to a graded approach. Additionally, inspectors should be trained in the enforcement procedures.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The Argentine legislative and regulatory framework for nuclear and radiation safety includes the Nuclear Act No 24.804, its Regulatory Decree No 1.390/98, as well as the Radioactive Waste Management Act No 25.018. These constitute the core of legally binding documents for nuclear and radiation safety.

Article 1 of the Nuclear Act establishes: "Concerning nuclear matters the State will establish the policy and perform the functions of research and development through the National Atomic Energy Commission and of regulation and control through the Nuclear Regulatory Authority".

The Nuclear Act specifies the roles and responsibilities of the main organizations in the nuclear field, including the authority and responsibility of ARN to develop and enforce regulatory safety standards and guides.

The management system of ARN contains a well-defined procedure (process P-Norm 01 Rev. 7 "Elaboration and Revision of Regulatory Standards and Guides) for developing, establishing and revising standards and guides. This process comprises the following main steps:

- Identification of necessity;
- Elaboration and Presentation of a Regulatory Initiative (RI);
- Elaboration of Draft Project of standard or guide;
- Achievement of internal consensus for the Draft project and approval by the Board of Directors;
- Submission of a Project Standard for public consultancy;
- Evaluation and incorporation of comments and proposals;
- Approval by ARN Board of directors; and
- Publication in the Official Gazette and on the ARN web page.

The procedure includes a transparent consultation process that strives to ensure that the intent and impact of a standard is fully understood by interested parties and provide them with the opportunity to contribute with comments and suggestions. However, this process does not include a requirement for consultation with interested parties on guides. In addition, it establishes a 15-day timeframe for the consultation, which is considered very short for an effective participation of the interested parties. Participation of the public is regulated by decree 1172/2002 "Access to the Public Information".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The period of public consultation for standards is only 15 working days, which may not provide sufficient time for effective participation.*	
(1)	**BASIS: GSG-6 para. 5.28 states that** *"Consultation includes several different stages, which should be followed to comply with legal and regulatory requirements and to give the process a better chance to succeed. To design a consultation procedure, the following aspects should be considered: […] Establishment of plans and time frames that are sufficient for effective participation and are adapted in accordance with the needs of the interested parties"*
S13	**Suggestion: ARN should consider defining time frames for consultation of interested parties that are sufficient for effective participation and are adapted in accordance with the needs of the interested parties.**

The guides are not subject to public consultation during their development and revision process (see R4 in section 3.8).

ARN publishes the complete set of standards and guides on their website in order to allow the public full access to the established regulatory framework.

In the past, ARN did not review the standards and guides in a systematic way, even when modifications of international and technical standards occurred. Identified gaps in the regulatory system were in the past addressed with the issuance of new conditions and requirements by means of official Resolutions, Requirements, Notes and MOUs that can be applied to specific licensees or to all of them. These documents are usually published on the ARN website. The IRRS team also noted the insufficient consideration of regulatory and operating experience.

During the self-assessment conducted in preparation of the mission, ARN identified a number of gaps with IAEA safety standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The standards and guides display a number of gaps in comparison with the IAEA framework. There is no formalized process in place which ensures that a systematic review of standards and guides is done.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Req. 33 states that** *"The Regulations and guides shall be reviewed as necessary to keep them up to date, with due consideration taken of relevant international safety standards and of technical standards and of relevant experience gained…"*
R13	**Recommendation: ARN should establish a formalized process to review and revise, as necessary, standards and guides to keep them up to date.**

Overall, ARN has a well-established regulatory framework that enables the effective regulatory oversight of nuclear facilities in Argentina. However, it lacks a systematic review and revision process to update it when appropriate.

Especially in the view of ongoing development and construction of new facilities (CAREM-25) and intended new-build of NPPs (Hualong-1), it is important that Argentina revises and complements its standards and guides to allow for high quality regulatory oversight.

In the self-assessment conducted in preparation of the mission, ARN identified that 30 standards and 4 guides have to be revised, and 34 new standards and 37 new guides have to be developed. Since then, ARN has issued 3 guides and 5 standards, including 3 on new topics not foreseen in the action plan. ARN has also 1 guide and 4 standards in advanced draft states. This means that out of 105 identified projects, only 5 have been finished in the last 5 years.

That evidences the lack of resources for a faster process for updating or developing standards and guides. The process will be very time-consuming and it is questionable if ARN will be able to achieve its goals with the present staffing in a timely manner.

The IRRS team was of the view that the resources allocated to develop standards and guides should be significantly increased. Recommendation R3 in Section 3.3 addresses this issue. Also, to ensure that compliance with international standards and guides will be achieved in the future, it is necessary to introduce a corresponding process in the management system of the regulating body. Recommendation Rx in Section x addresses this issue.

One of the few recently issued standards AR 10.6.1 rev. 0, entitled "Management System for Installations and Practices", specifies requirements for the licensees' management system and also introduces the concept of an integrated management system. The standard was issued in January 2020 and came into force as of April 1st, 2021. In the time between, ARN provided nine information events for interested parties (e.g. NPPs, research reactors, industrial users, medical field, waste and transport) addressed by the standard, aimed at promoting and facilitating the introduction of this standard:

These events were recorded and made available to potential users via email and internet. In addition, a video presentation was produced that is available on the website of ARN and on its YouTube Channel (https://www.youtube.com/watch?v=2HMsjj6MOlM), introducing the concept of an integrated management system and highlighting the main contents to the interested public.

The way the regulatory body introduced and presented this new standard AR 10.6.1 rev. 0 to the intended users and the public in a very systematic and innovative way was found remarkable for supporting the effective implementation by the licensees, and is considered a good performance.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

During the self-assessment ARN identified the need to revise several existing standards and guides as well as to develop a significant number of new standards and guides for NPPs. In the following lists the standards and guides relevant for nuclear power plants are listed and connected to the recommendations from the self-assessment.

ARN plans to develop the following new standards:

- Installations and Practice Safety Assessments.
- Decommissioning of Installations and Termination of Practices
- Preparedness and Response for Nuclear and Radiological Emergency
- Occupational Radiation Protection
- Site Assessment for Class I Installations
- Safety requirements for Spent Fuel Storage
- Safety requirements for nuclear reactor construction
- General safety requirements for NPP licensing
- Format and content of Safety Report for NPP
- Periodic Safety Review for NPP
- Safety requirements for the design of NPP
- Deterministic Safety Assessment for NPP
- Probabilistic Safety Assessment for NPP
- Operational limits and conditions for NPP
- Operation organization for NPP
- Design modifications in NPP

ARN plans to develop the following new guides:

- Guides associated with standard AR ”Management system for safety in the Installations and practices”
- Guides associated with the standard "Preparedness and response for nuclear and radiological emergency"
- Guide associated with the standard AR "Safety requirements for nuclear reactors construction ".
- Guide associated with the standard AR "Safety requirements for spent fuel storage".
- Verification of the radiological criteria for accidents (associated with AR 3.1.3)
- Systems classification
- Severe accidents management
- Ageing Management
- Maintenance
- Guide associated with the standard "Deterministic safety assessment for NPP".

- Guide associated with the standard "Probabilistic safety assessment for NPP".
- Guide associated with the standard “Decommissioning of nuclear power plants”

ARN plans to revise the following standards:

- AR 10.13.1. Standard for the physical protection of nuclear materials and installations.
- AR 10.14.1 Assurances of non-diversion of nuclear materials and materials, installations and equipment of nuclear interest.
- AR 0.11.1. Licensing of personnel of Class I installations
- AR 0.11.2. Psychophysical aptitude requirements for specific authorizations
- AR 0.11.3. Retraining of personnel at Class I installations
- AR 3.8.1 Preliminary tests and commissioning of nuclear power plants
- AR 3.9.1 General safety requirements for the operation of nuclear power plants
- AR 3.9.2 Relevant events communication at nuclear power plants
- AR 3.2.3. Fire protection at nuclear power plants
- AR 3.17.1 Decommissioning of nuclear power plants

The IRRS team found the self-assessment complete and thorough. As can be derived from the tables, the IRRS team concluded that there is evidence of the limitations and the lack of resources for implementing a faster process of updating and developing standards and guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing standards and guides do not sufficiently cover all requirements of the IAEA safety standards for nuclear power plants.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that** *“The Regulations and guides shall be reviewed as necessary to keep them up to date, with due consideration taken of relevant international safety standards and of technical standards and of relevant experience gained.”*
(2)	**BASIS: SSR-2/1 and SSR-2/2 as a whole**
R14	**Recommendation: ARN should revise existing standards and guides for nuclear power plants in accordance with the relevant IAEA safety standards.**

It is recommended to increase the resources allocated to revise and review standards and guides significantly (see R3 in section 3.3).

Also, to ensure that compliance with international standards and guides will be achieved in the future, it is necessary to introduce a corresponding process in the management system of the regulating body (see R13 in section 9.1).

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

Concerning Research Reactors there are standards and guides covering the following topics:

- Commissioning –AR Standard-4.8.1 Preliminary Testing and Commissioning of Critical Assemblies; AR Standard-4.8.2 Preliminary Testing and Commissioning of Research Reactors.
- Modification, maintenance, periodic testing and inspection – are covered by AR-4.9.1 Operation of critical assemblies and AR 4-9-2 Operation of research reactor
- Core management and fuel handling are covered by the operational standards for research reactors and critical assemblies AR- 4.9.1 and AR-4.9.2; that of requirement is Manual Maintenance. Core management and fuel handling partially design standards for research

reactors and critical assemblies AR 4-2-1 and AR- 4-2-2 and operational standards for research reactors and critical assemblies AR- 4-9-1 and AR 4-9-2; and

- Organization and personnel – requirements are in AR-0.11.1 Licensing of Class I Installations Staff and AR-10.6.1 Management System for Safety Installations and Practices.

The review showed that ARN partially met the requirements of SSR-3 concerning research reactors and has not issued all necessary regulatory requirements and guidance on research reactors for siting and design.

The IRRS team noted that ARN requirements are very general and only verification of internal documentation and interviews with inspectors allowed for their clarification. These requirements would deserve to be more detailed to facilitate their interpretation. At the moment, seven standards and four guidelines are under development (research reactors and critical assemblies).

Research reactor inspectors are involved in projects related to the development of new standards. However, the requirements contained in the draft standards are still quite general.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing standards and guides do not sufficiently cover all requirements of the IAEA safety standards for research reactors.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that** *"The Regulations and guides shall be reviewed as necessary to keep them up to date, with due consideration taken of relevant international safety standards and of technical standards and of relevant experience gained."*
(2)	**BASIS: SSR-3 as a whole**
R15	**Recommendation: ARN should revise existing standards and guides for research reactors in accordance with the relevant IAEA safety standards.**

9.4. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

The regulatory framework for fuel cycle facilities contains ARN standards applicable for Class I installations. These standards partially implement the concept of defence in depth; however, for fuel cycle facilities some gaps in the existing regulatory standards have been identified, with respect to design, siting, commissioning, operation and decommissioning of installations. There is no regulatory guidance on safety analysis and classification of systems, structures and components for fuel cycle facilities. The IRRS team observed evidence of informal use of the relevant IAEA safety standards as reference materials by ARN and licensees.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing standards and guides do not sufficiently cover all requirements of the IAEA safety standards for fuel cycle facilities.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that** *"The Regulations and guides shall be reviewed as necessary to keep them up to date, with due consideration taken of relevant international safety standards and of technical standards and of relevant experience gained."*
(2)	**BASIS: SSR-4 as a whole.**
R16	**Recommendation: ARN should revise existing standards and guides for fuel cycle facilities in accordance with the relevant IAEA safety standards.**

9.5. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The following standards and guides apply to radioactive waste management facilities:

- Standard AR 10.1.1 Basic radiation safety standard;
- Standard AR 0.0.1 Licensing of Class I installations;
- Standard AR 0.11.1 Licensing of Class I staff;
- Standard AR 0.11.2 Requirements on mental and physical fitness for specific authorizations;
- Standard AR 0.11.3 Retraining of Class I installations staff;
- Standard AR 10.12.1 Radioactive Waste Management;
- Standard AR 2.12.1 Radiological Safety criteria for the management of radioactive waste from industrial milling and mining installations;
- Standard AR 10.6.1 Management system for Safety in facilities and practices;
- Standard AR 10.16.1 Transport of radioactive materials;
- Guide AR 3 Conditions to be verified by the examining physicians according to the psychophysical profile of the specific functions. This regulatory guide contains information associated with standard AR 0.11.2;
- Guide AR 6 Generic exemption levels. This regulatory guide contains information associated with standard AR 10.1.1;
- Guide AR 8 Generic levels of clearance. This regulatory guide contains information associated with standard AR 10.1.1;
- Guide AR 10 Specialized training, programs and specific training for the licensing of Class I installations staff;
- Guide AR 13 Storage of radioactive Waste; and
- Guide AR 14 Design and development of the environmental radiological monitoring plan.

ARN recognizes that Requirement 15 of SSR-5 "Site characterization for a disposal facility", is not considered in the standards AR 10.12.1 "Radioactive Waste Management" and AR 10.10.1 "Site evaluations of nuclear power plants" at the level of detail requested by SSR-5. As a consequence, ARN has included in its action plan the following actions:

- The scope of standard for licensing Class I facilities should be enlarged to consider particularities of final disposal facilities.
- The scope of the standard for the site evaluation of nuclear power plants should be enlarged to all Class I installations, including specific requirements for radioactive waste storage.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The standards set up in AR 10.12.1 "Radioactive Waste Management", and AR 10.10.1, "Site evaluations of nuclear power plants" do not prescribe the required level of detail needed to support a general understanding of both the characteristics of the site for a disposal facility and how the site evolves over time.*	
(1)	**BASIS: SSR-5 Requirement 15 states that** *"The site for a disposal facility shall be characterized at a level of detail sufficient to support a general understanding of both the characteristics of the site and how the site evolve over time. This shall include its present condition, its probable natural evolution and possible natural events, and also human plans and actions in the vicinity that may affect the safety of the facility over the period of interest. It shall also include a specific understanding of the impact on safety features, events and processes associated with the site and the facility"*
R17	**Recommendation: ARN should establish regulatory provisions to consider site characterization for a disposal facility.**

9.6. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

ARN has published a number of standards and guides applicable to radiation sources facilities and activities, covering different topics for Class II practices. However, they have not been regularly updated. ARN has included in its action plan the development of guidance, where gaps have been identified, and review existing guidance when necessary.

The current guidance for radiation facilities and activities establishes the format and contents of the documents to be submitted by the applicant in support of an application for authorization. This guidance covers gamma radiography, other industrial applications, nuclear medicine, radiotherapy, transport and import/export of sources.

The current standards and guides for protection and safety include only general provisions for the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources, either as a result of radiological procedures for medical treatment of patients or as a consequence of an emergency. It was noted in the reference materials that aside from this, no specific guidance detailing the procedures to be followed in these situations are available; this should be developed in consultation with health authorities (see R13 in section 9.1).

9.7. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The following standards for decommissioning activities are applicable:

- Standard AR 10.1.1 Basic radiation safety standard
- Standard AR 10.6.1 Management System for Safety in installations and practices
- Standard AR 10.12.1 Radioactive waste management
- Standard AR 3.17.1 Decommissioning of nuclear power plants
- Standard AR 0.0.1 Class I installation licensing

For Class II and Class III installations, the following standards and guides are applicable:

- Standard AR 8.2.3 Operation of cobalt teletherapy installations
- Standard AR 8.2.4 Use of unsealed Radioactive Sources in Nuclear Medicine Installations
- Operation of Radiation Sources for Industrial Applications

The following guide is also applicable:

- AR 14 Design and development of an environmental radiological monitoring plan

A significant effort is being made by ARN to upgrade and improve its standards on decommissioning. In accordance with the information provided by ARN, the following standards and guides are under development:

- Decommissioning of installations and termination of practices
- Guide associated with standard AR “General safety requirements for the decommissioning of installations and termination of practices
- Guide “Decommissioning of nuclear power plants”
- Guide “Decommissioning of research reactors”
- Guide “Decommissioning of medical, industrial and research installations”

In addition, Standard AR 3.17.1 “Decommissioning of Nuclear Power Plants” is being revised and updated to extend its scope to all Class I facilities.

9.8. REGULATIONS AND GUIDES FOR TRANSPORT

ARN is the Competent Authority (CA) for the transport of Class 7 (radioactive material) dangerous goods within Argentina as defined in Act No 24.804 Article 16 a) and k). ARN covers all modes of transport (Air, Sea, Road and Rail) and is responsible for issuing standards related to transport of radioactive material.

The standard (AR 10.16.1) has been issued by ARN relating to transport of radioactive material which is currently at revision 3 and is based on IAEA SSR-6 2012 edition. ARN has a process for reviewing and updating AR 10.16.1 when SSR-6 is updated but at this time has decided that it is not a priority to update to the SSR-6 (Rev. 1) 2018 edition. This is due to the impact of the changes between editions having been assessed as not significant for internal transport activities. Air and Sea modes of transport into and within Argentina are carried out in accordance with international modal requirements which have been updated to match SSR-6 (Rev. 1) 2018 Edition and as such AR 10.16.1 is not fully compatible with the air and sea requirements.

The Ministry of Transport is responsible for vehicle standards and driver training for all classes of dangerous goods, via Traffic Law No. 24449 regulated by Decree 779/95, and the Resolution No. 195/97, but this aspect was not within scope of the mission.

Guidance has been issued by ARN to assist applications for package approvals, the guidance includes details of expected contents and structure of documentation as well as a form used for applying for approvals.

ARN has produced two documents which detail the emergency response actions to be taken by carriers/consignors in the event of a transport related incident. These forms are mandated for use by inclusion of a reference in both package approval certificates and in licences for facilities. ARN is also informed when approved packages are transported via a submitted form (F-TMR-09), this is over and above the requirements of SSR-6 and is enforced via a requirement on the certificate of approval.

There is no specifically defined process for licensees to report non-compliances in accordance with AR 10.16.1 Para 309.

Transport across borders, primarily with Brazil and Chile, is managed through formal communications between licensees and competent authorities. There are agreements in place for mutual acceptance of driver qualifications and oversight for radiation protection. The emergency arrangements for both countries are issued to drivers at the start of the journey.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ARN has decided not to update transport standard (AR 10.16.1 Rev 3) which is based on IAEA SSR-6 from 2012, to the current revision of the specific safety requirements, SSR-6 (Rev. 1), updated in 2018.*	
(1)	**BASIS: GSR Part 1 (Rev.1) para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience."*
(2)	**BASIS: GSR Part 3 Requirement 2, para 2.25 states that** *"The government shall ensure that the transport of radioactive material is in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material (the IAEA Transport Regulations) and with any applicable international conventions, taking into consideration other internationally endorsed standards and recommendations derived from the IAEA Transport Regulations."*
S14	**Suggestion: ARN should consider updating transport standards to be consistent with SSR-6 (Rev. 1).**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although there is a requirement for reporting to the competent authority under AR 10.16.1 para 309 b) (iv), ARN does not have a formal process in place for licensees to report non-compliances to the regulator.*	
(1)	**BASIS: GSR-3 Requirement 3 Para 2.36 states that** *"The regulatory body shall establish mechanisms for communication and discussion that involve professional and constructive interactions with relevant parties for all protection and safety related issues."*
S15	**Suggestion: ARN should consider putting in place a process for licensees to report non-compliances to the competent authority.**

9.9. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The Basic Radiation Safety Standard AR-10.1.1 establishes that if the design of radiological safety systems ensures that no worker can receive an effective dose greater than 5 mSv per year under normal operating conditions and no member of the public can receive an effective dose greater than 0.1 mSv per year, it is not necessary to demonstrate that the systems are optimized, unless explicitly required by the regulatory body. During the process of assessment of applications, the regulatory body commonly requests from applicants to implement additional measures that allow them to reduce doses as reasonably achievable even when those are expected to be under 5 mSv. However, the IRRS team observed that this process is not documented.

Dose constraints for occupational exposure may be established by ARN in cases it deems appropriate. There is no specific requirement or procedure for applicants, licensees or registrants to define and establish the applicable dose constraint. Nevertheless, it is a common practice that licensees and registrants propose an adequate dose constraint based on the results and the history of the occupational doses.

There are no requirements in the standards regarding the definition of investigation levels, either by the regulatory body or the licensees and registrants.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Standards do not require applicants, licensees or registrants to define and establish the applicable dose constraint that should be considered for the optimization process. ARN has not established procedures for when to require further optimization, when workers are not expected to receive an effective dose greater than 5mSv in one year. There are no provisions for requiring the employers, registrants and licensees to establish the appropriate investigation levels.*	
(1)	**BASIS: GSR Part 3 Requirement 1, para. 2.10 states that** *"For all exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that protection and safety is optimized."*
(2)	**BASIS: GSR Part 3 Requirement 21, para. 3.77 (b) states that** *"Employers, registrants and licensees: …* *(b) Shall establish and use, as appropriate, constraints as part of optimization of protection and safety."*
(3)	**BASIS: GSR Part 3 Requirement 24, para. 3.94 (b) states that** *"Employers, registrants and licensees, in consultation with workers, or through their representatives where appropriate:* *(b) Shall include in the local rules and procedures any relevant investigation level or authorized level, and the procedures to be followed in the event that any such level is exceeded."*
(4)	**BASIS: GSG-7 para. 2.10 states that** *"In planned exposure situations, in relation to exposures due to any particular source within a practice, protection and safety is required*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	to be optimized in order that the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures all be kept as low as reasonably achievable, …"
(5)	**BASIS: GSG-7 para. 3.32 states that** *"…Dose constraints should be set in consultation with those involved. … The establishment of constraints may be the result of interaction between the regulatory body, the affected operators and, where appropriate, workers' representatives. As a general rule, it would be more appropriate for the regulatory body to encourage the development of constraints for occupational exposure within particular industries and organizational groupings, subject to regulatory oversight, than to stipulate specific values of constraints."*
R18	**Recommendation: ARN should further develop the regulatory provisions, within the existing optimization process, for the definition of dose constraints and for investigation levels ensuring that the doses received by any worker are as low as reasonably achievable.**

ARN has implemented procedures to supervise the compliance of technical criteria applicable to the performance of technical service providers (e.g. individual monitoring, calibrations, tests). ARN issues review reports and organizes, promotes or requires participation in national or international intercomparison exercises.

The IRRS team was informed that personal dosimetry laboratories are authorized by the Ministry of Health. Cooperation between Ministry of Health and ARN could be improved and strengthened regarding the approval or accreditation of personal dosimetry services (see R1 in section 1.5).

However, there are no provisions for the formal approval or authorization of internal or external technical services used by the authorized parties for complying with the safety requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no provisions for the formal approval or authorization of internal or external technical services used by the facilities.*	
(1)	**BASIS: GSR Part 3 para. 3.73 (c) states that** *"The regulatory body shall be responsible, as appropriate, for:* *c) Authorization or approval of service providers for individual monitoring and calibration services;"*
(2)	**BASIS: GSG-7 para. 8.1 states that** *"Any technical service providers for protection and safety should be qualified by certain procedures. The services provided by technical service providers can be divided into two categories:* *(b) Calibration and testing and assay services, including:* *(i)Monitoring services, including individual monitoring, workplace monitoring and environmental monitoring;* *(ii)Calibration and calibration verification services for monitoring devices and radiation sources.*
(3)	**BASIS: GSG-7 para. 3.110 states that** *"… The regulatory body should give consideration to the establishment of a national accreditation procedure as a basis for the approval of dosimetry services…"*
S16	**Suggestion: ARN should consider developing provisions for ensuring the formal approval or authorization of technical services providers as appropriate.**

9.10. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The Standard AR 10.1.1, Rev.4 Basic radiation safety standard establishes the requirements for the protection of people and the environment against the harmful effects of ionizing radiation and for the safety of radiation sources. This standard applies to all facilities and practices regulated by ARN, in accordance with current legislation. This standard does not cover equipment specifically designed to generate X-rays, under the terms of Law No. 17,557, but includes linear accelerators for medical use that, as a result of its operation, give rise to or produce additional ionizing radiation to X-rays.

For medical practices, the Education and Training requirements for obtaining the individual permits are established in:

- Standard AR 8.11.1-Rev 2: Individual Permits for the Use of Radioactive Material or Ionizing Radiation on Humans;
- Standard AR 8.11. 2-Rev 0: Minimum Active Clinical Training Requirements for Obtaining Individual Permits for Medical Purpose; and
- Standard AR 8.11.3-Rev 0: Individual Permits for Specialists and Technicians in Radiotherapy Physics.

Although ARN is also issuing individual permits for competent personnel in nuclear medicine, currently a corresponding standard is in development and the process will be formalized by ARN.

ARN has published Standards for regulation of medical practices in Nuclear Medicine and Radiotherapy, which establish the requirements and responsibilities for facilities undertaking medical exposure:

- Standard AR 10.1.1 Basic Radiation Safety Standard Rev. 4;
- Standard AR 8.2.1 Use of Sealed Sources in Brachytherapy Rev. 0;
- Standard AR 8.2.2 Operation of Linear Accelerators for Medical Purposes Rev. 1;
- Standard AR 8.2.3 Operation of cobalt teletherapy Installations Rev. 3; and
- Standard AR 8.2.4 Use of Unsealed Radioactive Sources in Nuclear Medicine Installations Rev. 1.

ARN Standards do not address several requirements of GSR Part 3, such as requirements for periodic radiological reviews, Quality Assurance (QA) for imaging equipment and Treatment Planning Systems, Diagnostic Reference Levels for nuclear medicine, criteria and guidelines for Release patients undergoing therapeutic treatments, dose constrains for Carers and comforters, and for volunteers participating in a programme of biomedical research.

ARN Standards require the licensee to take all practicable measures to minimize the likelihood of unintended or accidental medical exposures and promptly investigate the unintended or accidental medical exposures. However, Guidance or criteria is not established by ARN on the type of ‘significant events’ that are reportable. The IRRS team observed there was no record of any unusual incident reported by a medical facility to ARN, or dissemination of any relevant information to licensees in this regard.

The ARN Standards AR 8.2.1 to 8.2.4 for operation of linear accelerator, cobalt teletherapy, brachytherapy and nuclear medicine were published around the year 2000 and ARN has identified that the current Standards require strengthening to cover the advancements in medical technology, e.g. the Standards for linear accelerator equipment do not cover the requirement of QA of Treatment Planning Systems used in radiotherapy, and do not have any requirements addressing advanced therapy techniques. ARN informed that a Standard on Radiation protection and safety in medical uses for ionizing radiation has been in development based on the IAEA safety standards.

The IRRS team was informed that the regulatory framework for facilities that carry out medical practices is under revision. A new generic standard was drafted that takes into account a closer approach to what

is required in GSR Part 3, although taking into consideration that ARN has no legal competence in health field.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no guidelines on the type of 'significant events' of unintended and accidental medical exposure that are reportable to ARN. Requirement for periodic radiological reviews, quality assurance for nuclear medicine imaging equipment and treatment planning systems are not addressed in the respective ARN Standards. DRLs for nuclear medicine, criteria and guidelines for release patients undergoing therapeutic treatments, dose constrains for carers and comforters, and for volunteers participating in a programme of biomedical research are not established.*	
(1)	**BASIS: GSR Part 3 Requirement 41 para 3.180 states that** *"Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures: (a) Any medical treatment delivered to the wrong individual……. (f) any failure of medical radiological equipment, failure of software or system failure, or… other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended".*
(2)	**BASIS: GSR Part 3 Requirement 41 para 3.181 (d) states that** *"Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.180: Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the…… the regulatory body, and to the relevant health authority if appropriate."*
(3)	**BASIS: GSR Part 3 Requirement 42 para 3.181 states that** *"Registrants and licensees shall ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiation technologists and the medical physicists. The radiological review shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility"*
(4)	**BASIS: GSR Part 3 Requirement 34 para 3.148 states that** *"The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging".*
(5)	**BASIS: GSR Part 3 Requirement 34 para 3.149 states that** *"The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established: (a) Dose constraints, to enable the requirements of paras 3.173 and 3.174, respectively, to be fulfilled for: (i) Exposures of carers and comforters ; (ii) Exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research. (b) Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources".*
R19	**Recommendation: ARN should revise its Standards taking into consideration the IAEA GSR Part 3 requirements for medical exposure.**

9.11. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

ARN has a well-developed set of regulations related to public exposure and has already identified the need for further developing their regulations to fully comply with the IAEA Safety Standards. Although the described regulatory framework is available for remediation/restoration, a document is under development compiling the content of the standards, mentioned guides and international documents on a single integrating document that addresses the remediation / restoration process. Regarding food and

drinking water the revision of Guideline AR 1 which contains information related to Standard AR 10.1.1-Rev. 4 is in progress; specifically, for this point it establishes derived levels for food and drinking water and the corresponding strategy for control.

ARN already calculates the radiological impact for the representative person regardless of their geographic location (inside or outside the national territory), so in general, a hypothetical radiological impact to the public outside the national territory would be expected to be considered by their technical staff. The current legal framework also appears to be sufficient to consider the transboundary radiologic impacts, since the country ratified in 1997 the Convention on Nuclear Safety, which states in its Art. 17 (iv) that:

"Each Contracting Party shall take the appropriate steps to ensure that appropriate procedures are established and implemented: (…)(iv) for consulting Contracting Parties in the vicinity of a proposed nuclear installation, insofar as they are likely to be affected by that installation and, upon request providing the necessary information to such Contracting Parties, in order to enable them to evaluate and make their own assessment of the likely safety impact on their own territory of the nuclear installation".

This legal instrument is very important for informing the neighbouring countries of the potential impacts of new nuclear installations close to the borders. However, GSR Part 3 (Req. 29, para. 3.124-a) goes further on its requirements for protecting the public and the environment when it extends the requirement set in the Convention on Nuclear Safety to any relevant source within a practice when it says that: "When a source within a practice could cause public exposure outside the territory or other area under the jurisdiction or control of the State in which the source is located, the government or the regulatory body: (a) Shall ensure that the assessment for radiological impacts includes those impacts outside the territory or other area under the jurisdiction or control of the State".

The IRRS team found that it is important that an explicit provision is present in ARN regulations to ensure that the regulatory body assess transboundary radiological impacts to the public and the environment whenever this impact is deemed significant (above the "trivial dose").

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although ARN already calculates the radiological impact for the representative person regardless of their location (inside or outside the national territory), there is no explicit regulatory provision to ensure that these calculations will always be required in the case the radiological impact to the public lies outside the national territory.*	
(1)	**BASIS: GSR Part 3 Requirement 29, para. 3.124 (a) states that** *"When a source within a practice could cause public exposure outside the territory or other area under the jurisdiction or control of the State in which the source is located, the government or the regulatory body: (a) Shall ensure that the assessment for radiological impacts includes those impacts outside the territory or other area under the jurisdiction or control of the State";*
S17	**Suggestion: ARN should consider establishing regulatory provisions for ensuring assessment of radiological impacts outside the territory of the country when a source within a practice could cause significant public exposure outside the territory or other area under the jurisdiction or control of the State in which the source is located.**

Although the environmental law has provisions for ensuring that contaminated legacy sites are considered and financed, ARN does not have regulations for identifying those persons or organizations responsible for implementing the remediation of areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures. The IRRS team was presented with a draft on a specific standard covering remediation of existing exposures, as included in the action plan. However, the draft standard is in its initial stages of development.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In the case of existing exposures, there are no regulatory provisions for identifying those persons or organizations responsible for implementing the remediation of areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures.*	
(1)	**BASIS: GSR Part 3 Requirement 49 states that** *"The government shall ensure that provision is made for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; …"*
R20	**Recommendation: ARN should establish regulatory provisions to ensure that those persons or organizations responsible for areas with residual radioactive material are identified and that remediation programmes and sustainable post-remediation control measures are established and implemented.**

9.12. SUMMARY

All areas of ARN's competence are covered by standards and a few regulatory guides.

Standards and guides presently do not reflect the IAEA Safety Standards and other relevant international requirements. Standards and guides, in many cases, do not provide detailed requirements and associated criteria.

The procedures to develop, amend and revise standards and regulatory guides are stringent and comply with the state of the art. Still missing is a well-defined review period to trigger regular updates to keep standards and guides up to date.

A comprehensive renewal and extension programme for all standards has been started, as foreseen in the action plan. To allow for a timely execution of that programme additional resources should be allocated as necessary.

The way ARN introduced and presented a new standard for supporting the effective implementation by the licensees was considered a good performance.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

A National System for Comprehensive Risk Management and Civil Protection (Sistema Nacional de Gestión Integral del Riesgo - SINAGIR) was created in 2016 (law 27287 of 20/10/2016) which aims to integrate the actions and to articulate the functioning of national governmental agencies, provincial governments, the Autonomous City of Buenos Aires and municipalities, non-governmental organizations and civil society, in order to strengthen and optimize actions to reduce hazards, and manage emergency situations and recovery activities. The SINAGIR integrates national, provincial and local organizations and services involved in emergency management; the Presidency is exercised by the National Executive Authority. The SINAGIR is composed of the National Council for Comprehensive Risk Management and Civil Protection and the Federal Council for Comprehensive Risk Management and the Civil Protection. The National Council for Comprehensive Risk Management and Civil Protection is the highest authority for decision-making and for coordination of national means. Its responsibility is to design, propose and implement public policies for global hazard management. It is also the authority that will declare an emergency.

The law 27287 also created a Network of Scientific and Technical Organizations for Comprehensive Risk Management (GIRCYT) to provide specific information to the two Councils making available their capacities, scientific and technical knowledge and information and to channelize the efforts and optimize the use of resources. GIRCYT is composed of public scientific and technical bodies, public and private universities, other recognized institutions and organizations in the academic field.

Regarding Emergency Preparedness and Response (EPR), the Sub-Secretariat of Civil Protection of the Nation is the national organization responsible for the coordination of emergencies of any type at national level, while the authority to regulate nuclear or radiological EPR is trusted by the National Law of Nuclear Activity, Act No 24.804 and its Regulatory Decree 1.390/98 to ARN. For intervention in nuclear or radiological emergencies the use of resources is coordinated together by ARN and the sub-secretariat of the Civil Protection of the Nation. The ARN functionally reports directly to the General Secretariat of the Presidency of the Nation

The IRRS team observed that the aspects related to nuclear and radiological emergencies is in development. The Sub-Secretariat of Civil Protection of the Nation and ARN are working towards the aim to develop a national nuclear and radiological emergency plan, a national protection strategy for radiological hazard and strategies for specific aspects such as the management of radioactive waste generated in emergency and by remediation activities. Such documents are not available to date and are needed to frame the emergency plans for installations and activities.

ARN has established recommendations (Recommendations for the Development of an Emergency Plan or Procedure for Nuclear and Radioactive Facilities - IRU-SIERYN-01), complying with the IAEA Standards, for the development of emergency plans or procedures by the operators of nuclear and radiation facilities. The hazard assessment carried out ended up, considering a graded approach, in a national categorisation of installations and activities that is not fully aligned with the Emergency Preparedness Categories set up by GSR Part 7 (Table 1). For the different national categories, IRU-SIERYN-01 defines relevant emergency classes in general accordance with the GSG-2 Appendix III, with the exception of the “site area emergency.” “Site area emergency” is used in the USIE forms to communicate events resulting in a major decrease in the level of protection for those on the site and in the vicinity of the site, but which are not sufficient to meet the criteria of a General Emergency.

The licensees of national category I to III facilities are required by ARN to establish an on-site emergency plan as well as an off-site emergency plan to cope with the radiological consequences of an accident having significance for the public and the environment. These plans must take into account, as appropriate, the characteristics of the facility, the site and the surroundings of the site (including infrastructure and population), and the external events that could significantly hamper the emergency response and foresee the measures and means available to control the emergency and mitigate its

consequences in their areas of application. For facilities belonging to the national category "Other facilities" or non-routine activities, the licensee must establish emergency procedures. The Division Intervention in Radiological and Nuclear Emergencies (SIERYN) receives these emergency plans or procedures from the operators of licensed facilities or activities for evaluation. ARN carries out verifications to ensure that the regulated companies comply with the provisions of the emergency plans or procedures in IRU-SIERYN-01. The development and approval of emergency plans is mandatory prior to licensing.

Afterwards, during the lifetime of the facility or the conduct of the activity, the EPR plans and procedures are subjected to regular control (during exercises) and are revised and updated at the request of ARN based on lessons learned and when new requirements or guides are issued or at the renewal of the licence, but at least every 5 years.

The frequency of exercises is established by the regulatory body based on to the hazard presented by each facility or activity in accordance with a graded approach. Category 1 facilities (NPP's) have an internal exercise each year and an external exercise every second year. To date, 39 external emergency exercises have been carried out involving the Atucha Nuclear Complex and the Embalse Nuclear Power Plant.

ARN and the operating organizations work together with external response organizations and local, regional and national governments to have off-site response plans consistent with the on-site approved Plan.

There are agreements established between different organizations and ARN. These agreements with national organizations, such as the Sub-Secretariat of Civil Protection of the Nation, the Argentine Army, the Argentine Navy, the National Gendarmerie, the Argentine Naval Prefecture, the National Meteorological Service, the Ministry of Health and the Provincial and Federal Police ensure the consistence between the on-site and off-site response plans.

The IRRS team was informed that, to date, there is no national nuclear and radiological emergency plan but that the development of such plan is in progress in the framework of SINAGIR.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A national nuclear and radiological emergency plan, a national protection strategy for radiological hazard and strategies for specific aspects, such as the management of radioactive waste generated in emergencies and by remediation activities, are under development.*	
(1)	**BASIS: GSR Part 7 Requirement 5 states that** *"The government shall ensure that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 7 para. 6.17 states that** *"…An emergency plan shall be developed at the national level that integrates all relevant plans for emergency response in a coordinated manner and consistently with an all-hazards approach. Emergency plans shall specify how responsibilities for managing operations in an emergency response are to be discharged on the site, off the site and across national borders, as appropriate. The emergency plans shall be coordinated with other plans and procedures that may be implemented in a nuclear or radiological emergency, to ensure that the simultaneous implementation of the plans would not reduce their effectiveness or cause conflicts. …"*
R21	**Recommendation: The Government should strengthen the formalization of the national plan for response against nuclear and radiological emergencies, through the coordination with relevant governmental organizations.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The categorization of facilities and activities in IRU-SIERIN-01 is not fully aligned with the Emergency Preparedness Categories (EPC) provided in Table 1 of the GSR Part 7. IRU-SIERIN-01 defines relevant emergency classes with the exception of the "site area emergency".*	
(1)	**BASIS: GSR Part 7 Requirement 4 states that** *"The government shall ensure that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 7 para. 4.19 states that** *"For the purposes of these safety requirements, assessed hazards are grouped in accordance with the emergency preparedness categories shown in Table 1. The five emergency preparedness categories (hereinafter referred to as 'categories') in Table 1 establish the basis for a graded approach to the application of these requirements and for developing generically justified and optimized arrangements for preparedness and response for a nuclear or radiological emergency."*
(3)	**BASIS: GSR Part 7 para. 5.14 states that** *"The operating organization of a facility or activity in category I, II, III or IV shall make arrangements for promptly classifying, on the basis of the hazard assessment, a nuclear or radiological emergency warranting protective actions and other response actions to protect workers, emergency workers, members of the public and, as relevant, patients and helpers in an emergency, in accordance with the protection strategy (see Requirement 5). This shall include a system for classifying all types of nuclear or radiological emergency."*
(4)	**BASIS: GSG-2 Appendix III para III.4 states that** *"Declaration of an emergency in any of these emergency classes should initiate a response that is considerably beyond normal operations. Four is the minimum number of classes. Each class initiates a distinctly different level of response".*
S18	**Suggestion: ARN should consider adopting the emergency preparedness categories and emergency classes, including "site area emergency", as set up in the IAEA safety standards.**

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

The EPR criteria are established through a series of standards as the Basic Standard AR 10.1.1 and Transport Standard AR 10.16.1. There are others specific requirements according to the facilities. The Recommendations for the Development of an Emergency Plan or Procedure for Nuclear and Radioactive Facilities (IRU-SIERYN-01) describes the minimum content necessary for the development of Emergency Plans or Procedures, required as mandatory documentation by ARN. These instructions are presented to facilitate the preparation of the response plan in the event of a radiological or nuclear emergency, in accordance with the guidelines of Standard AR 10.1.1. "Basic Radiological Safety Standard" Revision 4 and other applicable standards.

The content of the Emergency Plans or procedures includes, as applicable:

- a description of the objectives and scope of the Emergency Plan;
- the legal framework;
- the response objectives based on the criteria in AR 10.1.1. Rev. 4 and GSG-2;
- a description of the installation, activity carried out, material involved and number of licensed personnel;
- a drawing of the facility and its geographical location;
- the identification of possible existing risks;
- the concept and management of emergency operations

- the radiological hazard assessment and planning of response actions;
- the identification of roles and responsibilities;
- the coordination mechanism (applies only to Category I);
- a mechanism to immediately inform ARN of deviations from normal operation;
- the description of communications during the emergency;
- the medical aspects;
- the protection of emergency workers;
- the radiological monitoring and decontamination tasks;
- the logistic support;
- the regime of training, exercises and drills; and
- the timing and conditions for revision.

Conforming to the requirements of IRU-SIERYN-01, the plans and procedures establish the roles and responsibilities in preparedness and response in agreement with the regulatory authority and response organizations and describe the tasks of each action group, developing the first urgent measures.

ARN and the licensees collaborate with external response organizations and local, regional and national governments to insure the coordination of off-site response plans with the on-site response Plan. ARN has established agreements with different organizations, such as the Sub-Secretariat of Civil Protection of the Nation, the Argentine Army, the Argentine Navy, the National Gendarmerie, the Argentine Naval Prefecture, the National Meteorological Service, the Ministry of Health and the Provincial and Federal Police to ensure the consistency between the on-site and off-site response plans.

The scope, roles and responsibilities of organizations and/or external actors that participate in the response of the emergency are documented and updated according to the needs. The spokesperson(s) responsible for the communication in response must be identified. Moreover, these plans and procedures must ensure that no operation necessary to restore the safety of the facility is compromised based on the resources required.

ARN has developed an extensive and consistent training programme for the personnel of licensed installations or activities, predesignated emergency workers and other emergency workers from organisations susceptible to intervene in emergency (e.g. the Red Cross) explaining the radiological risk, the intervention procedures and rules of engagement (with due consideration of the requirements 106 to 111 of the AR Standard 10.1.1. Rev 4 regarding the potential exposure dose), the use of personal protective equipment (protective clothes, masks, iodine tablets, dosimeters…) and monitoring devices and the other available resources to safely accomplish their role and duties.

Threshold exposure values are established to avoid excessive radiological exposure of the emergency workers. When such thresholds are approached, the emergency worker (or the Director of the operations) needs to evaluate whether she/he (emergency worker) can continue his intervention or withdraw. The IRRS team was informed that some hundreds of electronic dosimeters with alarms are stored at NPP.

The IRRS team encourages the Government to ensure that a sufficient number of electronic dosimeters with alarm thresholds are available to be made available to those emergency workers who have to intervene in an emergency situation, wherever it occurs.

The emergency plans or procedures of the operators of licensed facilities or activities are to be provided to the Division Intervention in Radiological and Nuclear Emergencies (SIERYN) for evaluation. ARN verifies that the emergency plans or procedures comply with the requirements in IRU-SIERYN-01 before approval. The approval of emergency plans or procedures is mandatory prior to licensing. Afterwards, during the lifetime of the facility or the conduct of the activity, EPR arrangements are

controlled, revised and updated at the request of ARN, whether necessary, e.g. when new requirements or guides are issued or at the renewal of the licence, but at least every 5 years.

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

The regulatory body verifies the compliance of EPR on-site arrangements of the licensed installations and activities against the regulatory requirements before commencement of operation/activity. Afterwards, during the entire lifetime of the facility or the conduct of the activity, the regulatory body controls EPR on-site arrangements by the approval of the revisions and updates of the on-site emergency plan and by conducting inspections on EPR arrangements as described in Section 7 and observing and evaluating the exercises.

The IRU-SIERYN-01 contains requirements on the emergency plan, radiation protection competences, and notification and training of the staff. Compliance with these requirements is verified by SIERYN and ARN's inspectors from other relevant Divisions.

There are obligations stated in the recommendations for the development of an emergency plan or procedure for nuclear and radiological facilities or activities (IRU-SIERYN-01) to update and review the EPR plans. All revisions and updates have to be evaluated and approved by ARN.

As previously mentioned in sub-section 10.1, the IRRS team noticed that neither a national nuclear and radiological emergency plan, nor national protection strategy for radiological hazard or strategies for specific aspects such as the management of radioactive waste generated in emergency and by remediation activities are presently available although their development is in progress in the framework of SINAGIR (See R21 in section 10.1).

10.4. ROLES OF THE REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

ARN is designated by the Nuclear Act and Decree 1.390/98 as the authority to regulate nuclear or radiological emergencies preparedness and response. As established in this Decree and ARN Resolution 09/2006, ARN coordinates the local response actions and the involved organizations follow the directives of this officer in taking actions for public protection. At provincial or national level ARN acts as radiological adviser.

To fulfil its responsibilities, ARN maintains a permanent nuclear and radiological emergency intervention system (SIENYR), which is operational 24/7, to respond to situations that could expose people to radiation. As part of the SIENYR, the SIEN (comprising 20 experts including experts permanently present on the NPP sites) deals with emergencies caused by accidents at nuclear power plants, with consequences outside the facility while the SIER (18 experts) is covering radiological emergencies in minor facilities and activities, in public spaces or involving the population. The system functions are defined by Resolutions ARN 25/99 and 09/06 and work according to an operational procedure (G-IERN-01 R03); these documents are currently under revision.

The SIEN/SIER team of ARN plans and coordinates the implementation of response actions in conjunction with other organizations. If necessary (e.g. multiple accidents or long-lasting emergencies), these experts can appeal to some 200 experts belonging to other departments of the regulatory body.

When an emergency is declared in a nuclear facility, ARN-SIEN, according to operating procedure, designates a JOEN-ARN (Nuclear Emergency Operations Chief of the regulatory body) who, together with the JOEN-NA-SA (Nuclear Emergency Operations Chief of the operator of the NPP), manage the response during the first hours by implementing the precautionary and urgent protective actions in the PAZ (3 km in all directions) and the UPZ (up to 10 km) as foreseen in the approved emergency plan of the facility, i.e.:

- before release (Green Alert), automatic evacuation in the PAZ and preparation for sheltering, distribution of iodine tablets and preparation for access control in the UPZ, and informing population through FM radios;

- during the release (Red Alert), implementation of the sheltering, access control and stable iodine intake in the UPZ, and informing the population through FM radios.

After this period, ARN will take over the management of the off-site response as a member of the crisis management centre. ARN is responsible for the evaluation of consequences, to organize environmental measurements and sampling and to advise the decision-makers regarding the protective actions and other actions.

For emergencies in other facilities and activities or events in the public domain, the SIERYN has produced intervention procedures (f 127-r04 and f 129 r04) which describe the expected reaction of emergency services in response to a transport accident.

As part of the activities carried out in the preparation stage, ARN provides training to response organizations throughout the country, which can intervene as first responders in an emergency. Specific trainings are organized for different groups, according to their role and responsibility in response in the event of a nuclear or radiological accident; in this context a training of 'medical' people has been prepared and given to medical doctors and nurses, including the identification of acute radiation syndromes (ARS) and treatments to be given to victims.

Regarding the implementation of emergency measures triggered by a security event, ARN coordinates its interventions in the framework of SINAGIR.

Argentina is a party to the Conventions for Early Notification and Assistance and ARN is designated as the Competent Authority. ARN is the NWP and CA for USIE and participates in RANET.

The INES National Officer for Argentina belongs to the SIERYN-ARN.

ARN has developed an extensive training programme for emergency responders, such as radiation emergency first responders or the medical community (see GP1 in section 2.1). It offers on-demand training courses and workshops for its own staff and other organizations. ARN has the responsibility to inform the population concerning the nuclear risk and the protective actions (see also section 3.8).

10.5. SUMMARY

ARN participates to the National System for Comprehensive Risk Management and Civil Protection (Sistema Nacional de Gestión Integral del Riesgo - SINAGIR) which aims to integrate in an all hazard approach the actions and functions at all levels in order to strengthen and optimize actions aimed at the reduction of hazards, the management of crisis and recovery.

The Sub-Secretariat of Civil Protection of the Nation coordinates emergencies of any type, while ARN has the authority to regulate nuclear or radiological EPR (Nuclear Act and Decree 1.390/98). The two organisations coordinate together the use of resources for nuclear or radiological emergencies. ARN has its own standards and procedures to intervene in nuclear or radiological emergencies but, to date, there is neither national nuclear and radiological emergency plan nor a national protection strategy for radiological hazard and strategies for specific aspects such as the management of radioactive waste generated in emergency and by remediation activities. The development of such documents is in progress.

ARN has established recommendations (IRU-SIERYN-01), globally in line with the IAEA Standards, for the development of emergency plans or procedures by the operators of nuclear and radiation facilities. However, the categorisation of installations and activities based on the hazard assessment is not fully aligned with the Emergency Preparedness Categories set up by GSR Part 7. Also, for the different national categories, IRU-SIERYN-01 defines relevant emergency classes, in general accordance with the GSG-2 Appendix III, with the exception of the "site area emergency" that is not considered though this emergency class is used for communication in USIE forms.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

The Nuclear Act establishes the functions, the objectives, the powers and the obligations of the regulatory body. In this respect, ARN is responsible for the regulation and supervision of the nuclear activity in all matters related to radiological and nuclear safety, physical protection, and supervision of the use of nuclear materials, licensing and supervision of nuclear installations and international safeguards, as well as advising the National Executive Power in matters within its competence. A relevant provision regarding nuclear security is Article 16 mentioning the power to dictate the regulatory norms referring to radiological and nuclear safety, physical protection and control on the use of nuclear materials, licensing and control of nuclear installations, international safeguards, and transport of nuclear materials in radiological and nuclear safety and physical protection aspects.

11.2. REGULATORY OVERSIGHT ACTIVITIES

The Department of Radiological Safety, Security and Safeguards (GSRFS) is responsible for the coordination of the physical security/ protection related matters with the technical areas in the framework of the licensing process of the ARN. The coordination and interaction with other authorities and agencies with responsibility for security at national and international level belongs to the Directory Board through the Physical Protection Activity.

Both groups, the GSRFS Department and the Physical Protection Activity share the routine assessment and control activities. The Physical Protection sector within the ARN previously handled the two fundamental and differentiated issues through regulatory standards, AR 10.13.1, Rev 02 "Standard for the Security of Nuclear Materials and Installations " and AR 10.13.2, Rev 0 "Standard for Security of Sealed Sources", and just recently, the latter has been handled by the Sector on Sources.

In addition to the provisions of the legal framework that ensure regulatory interfaces between safety, security and safeguards, the licensing procedures in force ensure internal coordination between the ARN sectors dedicated to the licensing and control of nuclear and radioactive installations, so that each of them achieves its regulatory objectives.

The current regulations on security (Standard RA 10.13.2 - article 36 a) and Transport (Standard RA 10.16.1- article 108) establish that security measures may be instituted for reasons other than radiation safety cannot be detrimental to radiation emergency plans or radiation safety in general. It provides for interaction between the groups specialized in radiation safety and security to ensure that security measures do not interfere with safety measures and vice versa. In addition to the provisions of the legal framework that ensure regulatory interfaces between safety, physical security and safeguards, the licensing procedures in force ensure internal coordination between physical security and other ARN technical sectors, dedicated to licensing and control of nuclear and radioactive installations.

As a result of the legal framework in force, ARN is the point of contact (POC) for the Bureau of the Specialized Technical Group (GTE) on Illicit Trafficking of Radioactive / Nuclear Materials and for the IAEA Incident and Illicit Trafficking Database (ITDB). Finally, ARN is a member of an interdisciplinary group with the Ministry of Security, Ministry of Defence, Customs and Migration with the aim to define the threat at state level.

The ARN technical areas, such as transport, safeguards, medicine, gammagraphy, industrial, nuclear safety, in the areas of licensing, permits and authorizations, technical information on the installations and users, requirements, research, material inventories, databases, etc., interact with sectors on physical protection and security of sources, as appropriate and necessary. The regulations in force clearly establish the requirement of interaction between the groups specialized in safety, security and safeguards during the licensing process of installations or practices that operate with nuclear materials or radioactive sources. The expected result of such interaction is an adequate compatibility of the safety measures with the physical protection measures and a control system that allows to maintain a better account for the nuclear and sensitive materials and radioactive sources subject to regulations. The

licensing process for radioactive facilities provides for interaction between the groups specialized in radiation safety and security to ensure that security measures do not interfere with safety measures and vice versa.

With respect to the inspection and control process, the IRRS team was informed that each technical sector has an independent inspection schedule. All detected non-compliances are recorded in inspection reports and when corrective measures may generate interference in the physical security system or in the interlocks and/or restrictions required by radiation safety, the requirements to the user are discussed and agreed upon by both technical sectors. The Physical Protection sector within the ARN has an important role since it is part of the licensing stages of Nuclear and Radioactive facilities through compliance with the mandatory documentation.

The IDSPF / IDSSF Physical Protection System Design Report/Physical Security System Design Report is the main mandatory document. These ID forms are posted to the ARN website completely empty, so the user can download it, complete and send them to ARN for analysis, evaluation, and approval.

11.3. INTERFACE AMONG AUTHORITIES

ARN has established cooperation agreements with the state security forces through the Ministry of Security, GNA - National Gendarmerie of Argentina; PNA - Argentine Naval Prefecture; PFA - Argentine Federal Police; PSA - Airport Security Police; BRE of the PFA - Special Risks Brigade of the Argentine Federal Police Firefighters; and with Ministry of Defence (Armed Forces - Argentine Army).

ARN maintains in force a set of agreements and cooperation agreements with public hospitals having high level sealed sources and with the security forces. Among the latter, it is worth mentioning the agreements in force through the Ministry of Security with the Argentine Federal Police and the special Risk Brigade of the Fire Department, the Argentine Naval Prefecture with the National Gendarmerie, and through the Ministry of Defence, with the Argentine Army.

Any activities involving the use of ionizing radiation regulated by ARN must have emergency procedures or contingency plans. This is required as part of the licensing process and supervision of these activities. Also, the contingency plans developed by the facilities and for transport, must consider actions to follow in case of security related incidents.

In the event of radiological (or security related) emergencies in facilities other than nuclear power plants, or during transport of radioactive materials, ARN will take the necessary steps through its own Radiological Emergency Intervention System (SIER). In case of a security related event, the SIER will follow the instructions of the Minister of Security. In addition, ARN has created the Nuclear Emergency Intervention System (SIEN), which complements the SIER in compliance with the provisions of the Nuclear Act and its regulating decree.

ARN must approve contingency plans for the case of nuclear accidents, programmes to deal with emergencies and where necessary, the corresponding training of workers. Such plans should provide for active participation by the community of security forces and representatives of civil institutions in the area covered by such procedures. The municipal, provincial, and national authorities that may be linked to the preparation of such plans shall comply with the guidelines and criteria defined by ARN.

11.4. SUMMARY

There is an adequate legal and regulatory framework in Argentina to enable effective interfaces between safety and nuclear security and the state system of accounting for, and control of, nuclear material. ARN has an existing arrangement with the Ministry of Security and Ministry of Defence in case of lost and stolen sources and nuclear materials and in case of security related emergencies, as appropriate. There is an interface and interaction with the ARN's Radiological and Nuclear Emergencies sector when it is necessary to search for and safeguard stolen material or material with malevolent intentions. The ARN's Physical Protection sector interacts mainly with the state security agencies.

12. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS

12.1 GOVERNMENTAL AND LEGAL FRAMEWORK FOR SAFETY

The government of Argentina has developed and implemented an effective governmental and legal framework in response to the COVID-19 pandemic declared by the World Health Organization. The Government implemented immediate measures to deal with the COVID-19 emergency in Decree No. 297/20 "SOCIAL, PREVENTIVE AND MANDATORY ISOLATION (ASPO)." Subsequent Decrees (Nos. 325/2020, 355/2020, 408/2020, 459/2020, and 493/2020) extended the ASPO without substantial modifications.

In response to the National Decrees, the Board of Directors of ARN issued several resolutions defining alternative forms of work to continue fulfilling its mission. Pursuant to these decrees, ARN was able to include special measures for critical infrastructures, such as those related to nuclear and radiation safety. In addition, ARN confirmed that Nucleoeléctrica Argentina S.A. (NA-SA) and the National Atomic Energy Commission were adequately prepared to continue their operation under the restrictive conditions imposed by ASPO.

12.2 REGULATORY FRAMEWORK

The Board of Directors defined the priorities and adjusted ARN's guidelines to the regulations issued by the National Government and the recommendations of the Ministry of Health, the Ministry of Labour and the Superintendence of Occupational Risks. Through Resolution No. 190/20, the Board of Directors of ARN approved the General Protocol on Prevention and Safety Measures for Health Emergency by COVID-19 which was developed in coordination with the Work Conditions and Environment for Public Sector Commission (CyMAT) and an interdisciplinary group of ARN professionals. This Protocol established measures to protect ARN workers engaging in essential services and/or in-person activities during the ASPO. It also applied later to the gradual return to in-person work. The measures included identifying high risk workers, isolation according to the national procedure, in-person work authorization procedures, follow-ups, etc. Subsequent addendums to the COVID-19 Protocol were issued in 2020, 2021, and 2022. The Protocol was certified by the National Institute of Certification (IRAM), pursuant to national standard IRAM-3830-2020. The IRRS team considered this certification as a good performance (see section 4.7).

ARN prioritized its activities focusing on the following:

- on-site inspection programme targeted to facilities carrying out essential activities using risk-based approach;
- ensuring the control of sources when institutions interrupted their normal operation and could not take care of these in a timely manner;
- issuing import/export authorizations for radionuclides and transport of radioactive materials;
- maintaining the personnel dosimetry service; and
- maintaining and calibrating inspection equipment and laboratories.

ARN adjusted its provisions to maintain the critical infrastructure required to continue essential regulatory functions. Teleworking was introduced as the main form of work with the support of an improved IT infrastructure allowing the management of resources and remote procedures, payment of salaries, and supply of necessary goods and services, among others.

During the pandemic, ARN kept close and clear communication within the organization and with authorized parties. For internal communication purposes, a COVID-19 section covering protective and sanitary measures was included in the ARN internal website and a digital ARN monthly bulletin was launched to cover the main news and tasks of the different ARN sectors and work teams.

Communication with authorized parties continued without interruption through formal and informal communication channels including face-to-face, telephone, email and videoconferencing according to a

graded approach. The newly adopted means of communication with the authorized parties were published on the ARN external website, social media and online magazines of the nuclear sector.

12.3 REGULATORY FUNCTIONS

In line with the national health protocols and restrictions, ARN developed and implemented a contingency plan to ensure the continuity of regulatory activities. Through this plan, ARN ensured the oversight of regulated facilities and activities while adopting special measures introduced due to the COVID-19 pandemic. Consequently, ARN adjusted its activities by defining alternative forms of work that allowed it to continue fulfilling its mandate.

The Decrees allowed ARN to extend the validity of the authorizations and to suspend the established terms for the renewal of all authorizations granted by ARN including operating licenses, registrations, non-routine practice authorizations, individual permits, specific authorizations, and radioactive material transport approval certificates. In addition, the licensed entities were not required to submit the required documentation unless ARN expressly requested it.

In accordance with a graded approach, ARN reduced the frequency of inspections. ARN continued to supervise the planned and unplanned outages of NPPs, verified particular technical aspects of radiological protection on site, controlled disused sources and gave continuity to radiological and nuclear safety inspections at the three nuclear power plants in operation with slight modifications to the established approach. Typically, NPPs have two resident inspectors at each site; however, during the pandemic this was limited to one inspector to reduce the potential for exposure. In addition, specialist inspectors performed inspections remotely with the support of resident inspectors on site to reduce contact. The resident inspectors adhered to internal health and safety procedures, as well as to licensee procedures to reduce their risk including measuring temperature prior to entering the facility, wearing face masks, and keeping enough distance during interviews and discussions. A virtual inspection was performed in 2020 to maintain the regulatory control of waste management activities.

Safeguards inspections were also carried out as planned at the facilities that use nuclear materials, jointly by the Brazilian-Argentine Accounting and Control Agency (ABACC) and the International Atomic Energy Agency (IAEA), in compliance with international commitments. Environmental control was maintained through the corresponding monitoring activities, the operation of laboratories and the corresponding evaluations. The monitoring stations for the detection of nuclear tests (CTBT) under the responsibility of ARN continued to operate on a daily basis. Since September 2021, ARN has resumed face-to-face inspections in all facilities.

For licensing of authorized personnel, the Board of Directors instructed the Advisory Council of the Personnel of Relevant Facilities (CALPIR) and the Advisory Council for the Application of Radioisotopes and Ionizing Radiation (CAAR) to conduct their functions in a digital manner. The focus was set on the validity extension of all the specific authorizations granted to the personnel of the nuclear power plants and facilities making the terms for their renewal more flexible. The annual retraining of the licensed personnel of Class I facilities was carried out virtually, with a combination of presential/virtual exams depending on the facility, and with the active participation of the inspectors of each group. All the authorizations approved during the ASPO were issued digitally to optimize time and resources.

The most relevant regulatory decisions made by ARN through Resolutions of the Board of Directors were published on ARN’s website. In fact, ARN’s website and social media was expanded during the pandemic, having recognized that those channels are necessary to showcase ARN as an effective and transparent regulatory body for nuclear and radiological safety, security and safeguards.

12.4 EMERGENCY PREPAREDNESS AND RESPONSE

Amid the COVID-19 measures on social distancing and/or isolation, ARN's radiological and nuclear emergency response systems (SIEN and SIER), their environmental and assessment support laboratories as well as the CTBTO monitoring stations remained operational with rotation teams available to respond

to any situation likely to compromise the control of radioactive or nuclear materials. The communication media as well as the radiological and nuclear emergency response system were kept active and all radiological emergencies were attended.

As a key priority for ARN, nuclear emergency exercises were carried out virtually (e.g. Embalse 2020, Atucha 2021, research reactors such as RA-1 and RA-3) to train different response organizations on their roles and functions in a nuclear emergency and to enhance the coordination between the Nuclear Regulatory Authority (ARN) and Nucleoeléctrica Argentina S.A. (NA-SA). Different scenarios were used to train the access control to the emergency area, evacuation and sheltering of the population and schools, distribution and intake of iodine tablets, triage and radiological environmental monitoring. In addition, training courses were adapted to a virtual modality and reached more than 1200 people from response organizations (civil defence, firefighters, medical emergency services, police, etc). Within the framework of the Embalse 2020 and Atucha 2021nuclear emergency exercises, didactic information was provided in schools around the NPPs using e-learning tools, when required.

12.5 OVERVIEW AND MAIN CONCLUSIONS OF THE POLICY DISCUSSION

Considering that COVID-19 is the first pandemic of this scale in the nuclear industry, it is necessary to draw lessons learned on how regulatory bodies managed to maintain business continuity and how to ensure there is proactive response in case of a new pandemic situation in the future. As such, a policy discussion on the regulatory implications of pandemic situations was held to foster experience sharing and the exchange of lessons learned between the IRRS team and ARN. The discussions focused on the infrastructure required to enable teleworking, the adaptation of working methods and procedures considering COVID-19 measures, and the conduct of hybrid and remote regulatory inspections.

The main experiences and overall conclusions drawn from the discussion were:

- Limited IT infrastructure, remote access, availability of digital information and online approvals were identified as challenges of teleworking. As such, some office presence was still needed;
- The importance to prepare a business continuity contingency plan, the identification of essential personnel (location, health status and expertise) and the need to ensure IT infrastructure for remote work were highlighted;
- While some regulatory bodies postponed drills and emergency exercises during the pandemic, some others considered that a hybrid approach for emergency response was feasible when the essential personnel is identified and trained in advance;
- Teleworking had a significant impact in the working dynamics of the regulatory staff and their interaction with relevant stakeholders. Some regulatory bodies are adopting this flexibility to optimize resources within and outside the regulatory body while ensuring the continuity of effective regulatory activities;
- Some regulatory bodies conducted a prioritization analysis to adjust their inspection programme using a graded approach to enable them to conduct face to face inspections, hybrid inspections (inspections conducted in presence of resident or site inspectors, with a remote participation of other inspectors or regulatory experts) and/or remote inspections (video calls or recorded videos).

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
ZARZUELA Javier	Nuclear Safety Council (CSN)	jzj@csn.es
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LIAISON OFFICER		
SIRAKY Gabriela	Nuclear Regulatory Authority (ARN)	gsiraky@arn.gob.ar

GROUP PHOTO

APPENDIX II – MISSION PROGRAMME

First Week

Time	SAT	SUN 21.08	MON	TUE	WED	THU	FRI	SAT	SUN
9:00-10:00	Arrival of Team Members		Entrance Meeting	Interviews / Visits	Interviews / Visits	Interviews / Visits / DTC writes introductory parts	TM write Report TL and DTL review introductory part	• Discussing and improving Draft Report • Cross-Reading • TL, DTL, TC and DTC read everything	Free day, Social Event / Reading, Cross-reading of the
10:00-11:00									
11:00-12:00			Interviews				Draft text to TL		
12:00-13:00			Lunch with Host	Standing lunch					
13:00-14:00		Lunch Team Building: • 5 minutes/TM self-intro • Refresher training Initial Team Meeting: • Welcome • Meet host liaison officer • Mission logistics • Discussion of first impressions • Closing		Interviews + in-group discussions / Visits	Interviews + in-group discussion / Visits	Interviews + in-group discussions / Visits / DTC writes introductory parts	Policy Discussions	Finalisation of the Draft Report	
14:00-15:00									
15:00-16:00			Interviews				Secretariat edits the report Preliminary Draft Report Ready Cross-reading by TM		
16:00-17:00					Written preliminary findings delivered				
17:00-18:00			Daily Team Meeting	Daily Team Meeting	Daily Team Meeting: Discussion of findings	Daily Team Meeting	Daily Team Meeting		
18:00-20:00		Team Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	
20:00-24:00			Writing of the report	Writing of the report	Daily Team Meeting: Discussion of findings	Writing of the report	TM Read Draft	Secretariat edits the report	

Second Week

<table>
<tr><th></th><th>MON</th><th colspan="2">TUE</th><th colspan="3">WED</th><th colspan="2">THU</th><th>FRI 02.09</th></tr>
<tr><td>9:00-10:00</td><td rowspan="2">'Pandemic' Contributions

Discussion of Recommendations, Suggestions and Good Practises with counterparts by module</td><td colspan="2" rowspan="2">Cross-Reading of the Report TL, DTL, TC and DTC read everything
Finalisation</td><td colspan="3">Common read through and finalisation of the Report by the Team</td><td rowspan="2">Host reads Draft Report</td><td></td><td>Submission of the Preliminary Report</td></tr>
<tr><td>10:00-12:00</td><td colspan="3">Submission of the Draft to the Host</td><td>Team discusses the Mission and provides IAEA with feedback</td><td>Issuance of Press Release</td></tr>
<tr><td>12:00-13:00</td><td>Standing lunch</td><td colspan="2">Standing lunch</td><td colspan="3">Lunch</td><td colspan="2">Standing Lunch</td><td>Lunch</td></tr>
<tr><td>13:00-15:00</td><td>Policy Discussions</td><td rowspan="3">Discussion of the Report by the Team</td><td rowspan="3">TC, DTC prepare Executive Summary and exit presentation</td><td rowspan="3">Host reads Draft Report</td><td rowspan="3">TL finalises Executive Summary and Exit Presentation</td><td rowspan="3">TC Drafts the Press Release</td><td colspan="2">Written comments provided by the Host

Team meeting to discuss and resolve Host comments</td><td rowspan="5">Departure</td></tr>
<tr><td>15:00-17:00</td><td>Individual discussions of Recommendations, Suggestions and Good Practises with counterparts</td><td colspan="2">Plenary (Team + Host) to discuss Host comments and finalize the report</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting</td><td colspan="3">Discussion of Executive Summary and delivery to the Host</td><td colspan="2">Briefing of the Senior IAEA Manager; Finalisation of the press release and of the Preliminary Report</td></tr>
<tr><td>18:00-20:00</td><td>Dinner</td><td colspan="2">Dinner</td><td colspan="3">Farewell Dinner</td><td colspan="2">Dinner</td></tr>
<tr><td>20:00-21:00</td><td rowspan="2">Secretariat updates Report</td><td colspan="2" rowspan="2">Secretariat finalises Report</td><td colspan="3" rowspan="2">Free</td><td colspan="2" rowspan="2">Free</td></tr>
<tr><td>21:00-24:00</td></tr>
</table>

APPENDIX III – SITE VISITS

1. Embalse NPP
2. Atucha NPP
3. RA-1 RR
4. Radiotherapy Institute Mevaterapia - Oncología Radiante, Buenos Aires
5. ECRI Fuel Fabrication Facility
6. Dioxitek Radioactive Source Manufacturing Facility

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Carrie Safford	Cristina Domínguez	Mariana Arias, Analía Canoba and Marcela Medici
2.	**THE GLOBAL SAFETY REGIME**		
	Vangeline Parami	Pablo Zunino	Gabriela Acosta, Ana Molinari and Victoria Roston
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Rosa Sardella	Cristina Domínguez	Mariana Arias, Ma. Laura Duarte, Fernanda Navia, Antonio Oliveira, Ana Rojo, Leonardo Sobehart, Dora Vidal, y Stella Zárate
4.	**MANAGEMENT OF THE REGULATORY BODY**		
	Elizabeth Bodis	Nélida Serdeiro and Beatriz D´amico	Ana Ma. Bomben, Alexis Grcevic, Lorena Mangone, Christian Sileoni
5.	**AUTHORIZATION**		
	Olivier Larreynie	Adriana Politi	Patricia Vidal
6.	**REVIEW AND ASSESSMENT**		
	Naveed Maqbul	Mario Krimer and Víctor Ibarra	Patricia Vidal
7.	**INSPECTION**		
	John Burta	Diego de Hijes and Gerónimo Poletto	

	IRRS EXPERTS	Lead Counterpart	Support Staff
8.	**ENFORCEMENT**		
	Yvette Staal	Diego de Hijes and Cristina Domínguez	Mariana Arias and Gerónimo Poletto
9.	**REGULATIONS AND GUIDES**		
	Gerhard Roos	Lucía Valentino	Patricia Vidal
10.	**EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS**		
	Christian Vandecasteele	Walter Truppa	Alan Segato and Mónica Rodríguez
11.	**INTERFACE WITH NUCLEAR SECURITY**		
	Vangeline Parami	Sergio Menossi	
	RESEARCH REACTORS		
	Piotr Lesny	Daniel Bertelli	Laura Arlia and Laura Hortal
	NUCLEAR FUEL CYCLE FACILITIES		
	Tatiana Bogdanova	Analía Saavedra	Lucas Martiri
	RADIATION SOURCES		
	Pedro Rosario	Dora Vidal and María T. Alonso	
	RADIOACTIVE WASTE MANAGEMENT FACILITIES		
	Susana Solís Sanz	Marcela Médici and Facundo López Cantón	Daniela Alvarez and Erika Führ
	DECOMMISSIONING		
	Susana Solís Sanz	Marcela Médici and Daniela Alvarez	

	IRRS EXPERTS	Lead Counterpart	Support Staff
	TRANSPORT ACTIVITIES		
	Christopher Jones	Alejandro Fernández	
	OCCUPATIONAL EXPOSURE		
	Rosbell Bosh Robaina	Dora Vidal, Daniela Alvarez and Analía Saavedra	Lucas Martiri
	MEDICAL EXPOSURE		
	S. Mahalakshmi	Carolina Bianchi and Fabián Saule	Soledad Rodríguez Roldán and Laura Castro
	PUBLIC EXPOSURE		
	Eduardo Figueira da Silva	Analía Canoba and Daniela Alvarez	Marcela Medici

APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	R1	ARN and the MoH should improve coordination in the field of regulatory control of medical facilities and services, and when necessary, implement joint inspection.
	R2	Although there is financing from National Treasury as provided for in the successive national Budget Laws, the Government should develop provisions to establish a fiduciary fund for securing financial resources for decommissioning, and management of radioactive waste and spent fuel.
2. THE GLOBAL SAFETY REGIME	GP1	ARN's outstanding education and training programme in radiation and nuclear safety that involved Latin America and the Caribbean is considered a good practice in promoting and enhancing safety globally.
	S1	ARN should consider establishing provisions to use feedback from national and international operating and regulatory experience for all facilities and activities, as well as for reporting in a timely manner relevant information and lessons learned from operating and regulatory experience to international knowledge and reporting networks.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	R3	ARN should bring together and complement the existing provisions for human resources management into a comprehensive human resources plan in order to ensure sufficient qualified and competent staff are allocated in relevant areas in accordance with a graded approach to discharge all its responsibilities.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S2	**ARN should consider expanding the national dose registry to facilities of all classes and establishing additional provisions to record and retain all information as required.**
	R4	**ARN should establish and implement regulatory provisions to consult interested parties, including the public, during the regulatory decision-making process, as appropriate.**
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**S3**	**The regulatory body should consider developing a comprehensive organizational safety policy in a single document.**
	R5	**ARN should complete its management system to ensure that all relevant processes are identified and documented.**
	R6	**ARN should regularly conduct assessments of leadership for safety and of culture for safety at all levels of the organization.**
5. AUTHORIZATION	**R7**	**ARN should supplement its regulatory provisions to provide the applicants with more clarity and better availability of information on all the major aspects to be dealt with at all steps of the licensing process, including that an adequate demonstration of safety should be required to support any application for authorization of all facilities or activities.**
	S4	**ARN should consider developing a comprehensive national register of radioactive sources and radiation generators under its regulatory oversight.**
	S5	**ARN should consider developing provisions regarding the incorporation, at the design stage, of features to facilitate the future decommissioning of facilities other than nuclear power and research reactors.**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S6	**ARN should consider establishing requirements and criteria for termination of the authorization for decommissioning.**
6. REVIEW AND ASSESSMENT	**S7**	**ARN should consider developing comprehensive guidance for its staff to review and assess licence applications submitted for all nuclear installations and radiation facilities.**
	S8	**ARN should consider establishing provisions in its management system for application of a graded approach in review and assessment process.**
	S9	**ARN should consider issuing guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization for nuclear installations.**
	R8	**ARN should develop a formal process to perform integrated safety assessments, as referred in GSR Part 1 (Rev. 1), periodically by combining the results of review and assessment and inspection to identify trends and draw conclusions on safety of facilities and activities in a systematic manner, in accordance with graded approach.**
	R9	**ARN should require applicants to perform an independent verification of safety assessments in accordance with a graded approach before submission to the regulatory body.**
	S10	**ARN should consider updating its regulatory guidance on the scope of the safety assessments for all Class II practices to ensure it considers normal operations, anticipated operational occurrences and accident conditions.**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
7. INSPECTION	R10	ARN should further systematize the training and qualification of inspectors to ensure that all inspectors possess all the necessary competence to perform their duties.
	S11	ARN should consider documenting the scope and objectives of a transport compliance inspection and convey this information to all parties involved in the transport of radioactive material.
	R11	ARN should formalise the methodology by which transport inspection plans are developed in accordance with a graded approach.
	S12	ARN should consider verifying in all facilities the implementation of the workers' health surveillance programmes, and when required, of special arrangements.
8. ENFORCEMENT	R12	ARN should bring the whole range of the possible enforcement actions under a comprehensive enforcement policy for responding to all types of non-compliances according to a graded approach.
9. REGULATIONS AND GUIDES	S13	ARN should consider defining time frames for consultation of interested parties that are sufficient for effective participation and are adapted in accordance with the needs of the interested parties.
	R13	ARN should establish a formalized process to review and revise, as necessary, standards and guides to keep them up to date.
	R14	ARN should revise existing standards and guides for nuclear power plants in accordance with the relevant IAEA safety standards.
	R15	ARN should revise existing standards and guides for research reactors in accordance with the relevant IAEA safety standards.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R16	**ARN should revise existing standards and guides for fuel cycle facilities in accordance with the relevant IAEA safety standards.**
	R17	**ARN should establish regulatory provisions to consider site characterization for a disposal facility.**
	S14	**ARN should consider updating transport standards to be consistent with SSR-6 (Rev. 1).**
	S15	**ARN should consider putting in place a process for licensees to report non-compliances to the competent authority.**
	R18	**ARN should further develop the regulatory provisions, within the existing optimization process, for the definition of dose constraints and for investigation levels ensuring that the doses received by any worker are as low as reasonably achievable.**
	S16	**ARN should consider developing provisions for ensuring the formal approval or authorization of technical services providers as appropriate.**
	R19	**ARN should revise its Standards taking into consideration the IAEA GSR Part 3 requirements for medical exposure.**
	S17	**ARN should consider establishing regulatory provisions for ensuring assessment of radiological impacts outside the territory of the country when a source within a practice could cause significant public exposure outside the territory or other area under the jurisdiction or control of the State in which the source is located.**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R20	**ARN should establish regulatory provisions to ensure that those persons or organizations responsible for areas with residual radioactive material are identified and that remediation programmes and sustainable post-remediation control measures are established and implemented.**
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	**R21**	**The Government should strengthen the formalization of the national plan for response against nuclear and radiological emergencies, through the coordination with relevant governmental organizations.**
	S18	**ARN should consider adopting the emergency preparedness categories and emergency classes, including "site area emergency", as set up in the IAEA safety standards.**

APPENDIX VI – COUNTERPART'S REFERENCE MATERIAL USED FOR THE REVIEW

NATIONAL LEGISLATION	
Act 14467	Ministry Of The Interior - Decrees - Laws - Validation
Act 17048	Vienna Convention on Civil Responsibility on Nuclear Damage
Act 17557	General provisions – X rays
Act 19549	State - National Public Administration - Procedural Law - Administrative Procedure Law
Act 21664	Occupational Health and Safety
Act 22498	The National Atomic Energy Commission Shall Operate As An Autarkic Entity
Act 23731	Approval of the Convention on Early Notification of a Nuclear Accident
Act 24046	Approval of an Agreement with Brazil for Peaceful Uses of Nuclear Energy
Act 24051	Dangerous Waste
Act 24113	Approval of an Agreement and Protocol with Brazil for application of Safeguards
Act 24776	Approval of the Convention on Nuclear Safety adopted in Vienna
Act 24804	National Law of Nuclear Activities
Act 25018	Act National Law on Radioactive Waste Management Regime
Act 25188	Ethics in the Exercise of the Public Function
Act 25279	Approval Joint Convention
Act 25313	Approval of the Protocol to Amend the Vienna Convention
Act 25675	National Environmental Policy
Act 25886	Criminal Code
Act 26640	Approval of the Convention on The Physical Protection of Nuclear Material
Act 26976	Approval of the International Convention for the Suppression of Acts of Nuclear Terrorism
Act 27275	Right of Access to Public Information
Act 27287	National System for Integrated Risk Management and Civil Protection
NATIONAL DECREES	
87/17	National Public Sector Digital Platform
383/17	National System for Integrated Risk Management and Civil Protection
603/92	Regime for the Control of Sensitive Exports and War Materials
634/07	Regulatory Fee Regime
842/58	Regulations for the use of Radioisotopes and ionizing radiation CNEA
1172/03	Access to Public Information
1390/98	Implementation Nuclear Act
1540/94	Creation of the National Nuclear Regulatory Board and constituting the Utility Nucleoeléctrica

5071/57	Ratifying the Statute of the International Atomic Energy Agency Subscribed by Argentina	
6320/68	Public Health (Act N° 17557)	
8566/61	Incompatibilities - Schedule - General Directorate Of The Civil Service Of The Nation	
10936/50	Ministry of Technical Affairs	
ARN REGULATORY STANDARDS		
AR 0.0.1.	Class I Facilities Licensing	Revision 2
AR 0.11.1.	Licensing of Class I facility personnel	Revision 3
AR 0.11.2.	Psychophysical fitness requirements for specific licenses	Revision 2
AR 0.11.3.	Retraining of personnel of Class I facilities.	Revision 1
AR 0.11.4.	Licensing of personnel of Class II and Class III Nuclear Fuel Cycle facilities.	Revision 0
AR 2.12.1.	Radiation safety criteria for the management of radioactive waste from mining and manufacturing facilities	Revision 0
AR 3.1.1.	Occupational Exposure in Nuclear Power Reactors	Revision 2
AR 3.1.2.	Limitation of Radioactive Effluents in Nuclear Power Reactors	Revision 2
AR 3.1.3.	Radiological criteria for nuclear power reactor accidents	Revision 2
AR 3.2.1.	General Safety Criteria for the Design of Nuclear Power Reactors	Revision 2
AR 3.2.3.	Fire safety in nuclear power reactors	Revision 2
AR 3.3.1.	Nuclear power reactor core design	Revision 2
AR 3.3.2.	Nuclear power reactor heat removal systems	Revision 2
AR 3.3.3.	Primary Pressure Circuit in Nuclear Power Reactors	Revision 1
AR 3.3.4.	Nuclear Power Reactor Fuel Element Safety	Revision 1
AR 3.4.1.	Nuclear power reactor safety-related instrumentation and protection systems	Revision 1
AR 3.4.2.	Extinguishing system for nuclear power reactors	Revision 1
AR 3.4.3.	Nuclear Power Reactor Containment System	Revision 1
AR 3.5.1.	Essential power supply in nuclear power reactors	Revision 1
AR 3.7.1.	Timeline of documentation to be submitted prior to commercial operation of a nuclear power reactor	Revision 1
AR 3.8.1.	Preliminary testing and commissioning of nuclear power reactors	Revision 1
AR 3.9.1.	General safety criteria for the operation of nuclear power reactors	Revision 1
AR 3.9.2.	Communication of relevant events in nuclear power reactors	Revision 1
AR 3.10.1.	Earthquake protection in nuclear power reactors	Revision 1
AR 3.17.1.	Decommissioning of nuclear power reactors	Revision 2
AR 4.1.1.	Occupational exposure in nuclear research reactors	Revision 0
AR 4.1.2.	Limitation of radioactive effluents in nuclear research reactors	Revision 1

AR 4.1.3.	Radiological criteria for research reactor accidents	Revision 2
AR 4.2.1.	Design of critical assemblies	Revision 1
AR 4.2.2.	Research reactor design	Revision 1
AR 4.2.3.	Fire safety in research reactors	Revision 2
AR 4.5.1.	Research reactor electrical power supply system design	Revision 1
AR 4.7.1.	Timeline of documentation to be submitted prior to research reactor operation	Revision 1
AR 4.7.2.	Timeline of documentation to be submitted prior to operation of a critical assembly	Revision 0
AR 4.8.1.	Preliminary testing and commissioning of critical assemblies	Revision 1
AR 4.8.2.	Preliminary testing and commissioning of research reactors	Revision 1
AR 4.9.1.	Operation of critical assemblies	Revision 1
AR 4.9.2.	Operation of nuclear research reactors	Revision 2
AR 5.1.1.	Occupational exposure in Class I particle accelerators	Revision 1
AR 5.7.1.	Timeline of documentation to be submitted prior to particle accelerator operation	Revision 1
AR 6.1.1.	Occupational Exposure from Class I Radioactive Facilities	Revision 1
AR 6.1.2.	Limitation of Radioactive Effluents from Class I Radioactive Facilities	Revision 1
AR 6.2.1.	Design of fixed irradiation plants with mobile irradiation sources placed underwater	Revision 2
AR 6.7.1.	Timeline of documentation to be submitted prior to operation of an industrial irradiation plant	Revision 1
AR 6.9.1.	Operation of fixed irradiation plants with mobile underwater irradiation sources	Revision 2
AR 7.9.1.	Operation of industrial gammagraphy equipment	Revision 3
AR 7.9.2.	Operation of radiation sources for industrial applications	Revision 0
AR 7.11.1.	Individual permits for industrial gammagraphy equipment operators	Revision 4
AR 7.11.2.	Individual permits for operators of radiation sources for industrial applications	Revision 0
AR 8.2.1.	Use of sealed sources in brachytherapy	Revision 0
AR 8.2.2.	Operation of medical linear accelerators	Revision 1
AR 8.2.3.	Operation of telecobaltotherapy facilities	Revision 3
AR 8.2.4.	Use of unsealed radioactive sources in nuclear medicine facilities	Revision 1
AR 8.11.1.	Individual permits for the use of radioactive material or ionizing radiation in human beings.	Revision 2
AR 8.11.2.	Minimum requirements for active clinical training for individual permits for medical purposes	Revision 0
AR 8.11.3.	Individual permits for specialists and technicians in radiotherapy physics.	Revision 0

AR 10.1.1.	Basic Radiation Safety Standard	Revision 4
AR 10.6.1.	Management system for safety in facilities and practices	Revision 0
AR 10.10.1.	Site assessment of nuclear power reactor sites	Revision 0
AR 10.12.1.	Radioactive Waste Management	Revision 3
AR 10.13.1.	Physical protection standard for nuclear materials and facilities	Revision 1
AR 10.13.2.	Standard for the physical security of sealed sources	Revision 0
AR 10.14.1.	Guarantees of non-diversion of nuclear materials and of materials, facilities and equipment of nuclear interest	Revision 0
AR 10.16.1.	Transport of radioactive materials	Revision 3
ARN RESOLUTIONS		
09 /06	Nuclear Regulatory Authority Crisis Committee	
24 /99	Sanctions Regime for Non-Compliance of Standards on Rad and NS, PP, SG and Non-Proliferation in Relevant Installations	
25 /99	System For Intervention In Nuclear Emergencies	
32 /02	Sanctions Regime for Class II& III Installations, Non Routine Practices and Transport of Radioactive Materials	
41 /99	Regulation of the Disciplinary Regime for the Personnel of the National Atomic Energy Commission	
63 /99	Sanctions Regime for Nuclear Power Plants	
66 /04	Import Or Export Requirements	
76 /08	Licensing And Inspection Fees Regime	
159 /22	Procedure for the Investigation of Non-Compliance with Regulatory Norms	
180 /13	Personnel Involved In Individual Dosimetric Control	
247 /20	Modification Of 268-19. Public Health Emergency	
517 /05	Organizational Structure - Approval	
1946 /05	Federal Administration of Public Revenues, Import and Export Operations	
ARN GENERAL DOCUMENTS		
Organizational Chart ARN 2022		
Institutional Strategic Plan 2021-2025		
ARN Process Map 2019		
Quality Management Manual		
List of Quality Management System Procedures		
Nuclear Safety Report 2019		
ARN Annual Report 2020		
ARN Annual Report 2021		

ARN First Report – Management Control – 2021
ARN Second Report – Management Control – 2021

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Leadership and Management for Safety, General Safety Requirements Part 2, No. GSR Part 2, IAEA, Vienna (2016)
4.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No. GSR Part 3, IAEA, Vienna (2014).
5.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Radioactive Waste, General Safety Requirement Series Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Facilities, General Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014)
8.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirement Series No. GSR Part 7, IAEA, Vienna (2015)
9.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Site Evaluation for Nuclear Installations, Specific Safety Requirement Series No. SSR-1, IAEA, Vienna (2003)
10.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Power Plants: Design, Specific Safety Requirements Series No. SSR-2/1 (Rev. 1), IAEA, Vienna (2016)
11.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Research Reactors, Specific Safety Requirements Series No. SSR-3, IAEA, Vienna (2016)
13.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements Series No. SSR-4, IAEA, Vienna (2017)
14.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Disposal of Radioactive Waste, Specific Safety Requirements Series No. SSR-5, IAEA, Vienna (2011)
15.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements Series No. SSR-6, IAEA, Vienna (2012)
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17.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
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25.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - The Management System for the Disposal of Radioactive Waste, Safety Guide Series No GS-G-3.4, IAEA, Vienna (2008)
26.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)
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28.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Modifications to Nuclear Power Plants, Safety Guide Series No NS-G-2.3, IAEA, Vienna (2001)
29.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide Series No NS-G-2.8, IAEA, Vienna (2002)
30.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)
31.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide Series No. RS-G-1.10, IAEA, Vienna (2008)
32.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Borehole Disposal Facilities for Radioactive Waste, Safety Guide Series No SSG-1, IAEA, Vienna (2009)
33.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
34.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
35.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
36.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
37.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)
38.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Spent Nuclear Fuel, Safety Guide Series No SSG-15 (Rev. 1), IAEA, Vienna (2020)

39.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Periodic Safety Review for Nuclear Power Plants, Safety Guide Series No SSG-25, IAEA, Vienna (2013)
40.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26, IAEA, Vienna, (2014)
41.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, Safety Guide Series No SSG-40, IAEA, Vienna (2016)
42.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-41, IAEA, Vienna (2016)
43.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, Safety Guide Series No SSG-45, IAEA, Vienna (2019)
44.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-47, IAEA, Vienna (2018)
45.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants, Safety Guide Series No SSG-48, IAEA, Vienna (2018)
46.	**INTERNATIONAL ATOMIC ENERGY AGENCY** –Decommissioning of Medical, Industrial and Research Facilities, Safety Guide Series No SSG-49, IAEA, Vienna (2019)
47.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Operating Experience Feedback for Nuclear Installations, Safety Guide Series No SSG-50, IAEA, Vienna (2019)
48.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Accident Management Programmes for Nuclear Power Plants, Safety Guide Series No SSG-54, IAEA, Vienna (2019)
49.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material, Safety Guide No TS-G-1.2 (2002)
50.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
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52.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna, (2009)
53.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2009 Edition), Safety Guide No TS-G-1.6 (Rev.1), IAEA, Vienna, (2014)
54.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No WS-G-6.1, IAEA, Vienna (2006)
55.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)
56.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)

APPENDIX VIII – ORGANIZATIONAL CHART