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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

ITALY

ROME, ITALY

21 November to 2 December 2016

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA Integrated Regulatory Review Service IRRS

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Review Service
IAEA IRRS

REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
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Integrated Regulatory Review Service

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Mission dates:	*21 November to 2 December 2016*
Regulatory body visited:	*National Institute of Environmental Protection and Research (ISPRA)*
Location:	*Rome, Italy*
Regulated facilities and activities in the mission scope:	*Radiation Sources in Industrial and Medical Facilities, Emergency Preparedness and Response, Research Reactors, Waste Management and Decommissioning, Transport, Occupational Exposure, Public and Environmental Exposure.*
Organized by:	*IAEA*

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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 Italy, an international team of senior safety experts met representatives of the Government and the Institute for Environmental Protection and Research/Nuclear, Technological and Industrial Risk Department (ISPRA), the main regulatory authority in Italy, from 21 November to 2 December 2016 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this mission was to perform a peer review of the Italian regulatory framework for nuclear and radiation safety.

The mission took place at the ISPRA Headquarters in Rome. Meetings were organized with the State Undersecretary of the Ministry of Environment, Land and Sea Protection and other representatives of the same Ministry. Additional meetings were organized with representatives of the Ministry of Economic Development, the Ministry of Labour and Social Affairs, the Ministry of Interior and the Ministry of Health. Meetings with representatives of the Prefecture of Rome, of the National Civil Protection Department, of the Piedmont Region and of the Environmental Protection Agency of this region also took place.

The IRRS mission covered all civilian nuclear and radiation source facilities and activities regulated in Italy. The review compared the Italian legal and regulatory framework for protection and safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and their Italian counterparts in the areas covered by the IRRS.

The IRRS review team consisted of 14 senior regulatory experts from 10 IAEA Member States, 3 IAEA staff members and an IAEA administrative assistant.

The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, public and environmental exposure control, transport of radioactive material, waste management and decommissioning. The IRRS review addressed all facilities and activities regulated by ISPRA such as radiation sources, research reactors, waste management facilities and nuclear facilities under decommissioning. The control of medical exposure was out of the scope of the mission.

The IRRS mission included discussion of two policy issues on "Transparency of the regulatory body and relation with stakeholders" and "Siting process of disposal facilities and participation of the public".

The mission included observations of regulatory activities, interviews and discussions with staff of ISPRA. Activities included visits to the Nucleco waste management facility and the TRIGA RC-1 research reactor in Casaccia, to the Gemelli Hospital in Rome and to the Garigliano nuclear power plant under decommissioning. The IRRS team members observed regulated activities and the performance of inspection activities, and also held discussions with the licensee personnel and management.

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

transparent manner. The IRRS team members observed that their counterparts were committed to providing effective oversight and other regulatory functions.

It was recognized that the major challenges for Italy are the insufficient resources for the regulatory body to perform its functions and the need to implement strategies and plans for decommissioning of nuclear facilities and to develop and implement disposal facility for radioactive waste. The most significant challenges for ISPRA, acknowledging the limited resources, are the establishment of procedures and guides, for external and internal use, and the implementation of legislative provisions that are still pending.

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

The good practices identified by the IRRS review team include:

- the use of the *"state of the art"* standards in the field of decommissioning and waste management;
- the development and use of a comprehensive data base and the related tools for extracting and analysing transport safety issues;
- the Italian system for education and training of qualified experts which is of high quality in radiation protection.

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

The Government should:

- provide the regulatory body with sufficient competent staff for the proper and timely implementation of its assigned responsibilities;
- continue the efforts to develop a national policy and strategy for safety and national policies and strategies for decommissioning and management of radioactive waste including disposal;
- complete the legal framework in regards to approval of technical services, establishment of national data bases related to safety and improvements in aspects of the authorization process.

The Regulatory Body should:

- establish and implement an integrated management system;
- strengthen the regulatory framework for review and assessment - including periodic safety review, authorization, inspection, emergency preparedness and response, and for the occupational and public exposure control;
- improve existing communication strategies.

The IRRS review team findings are summarized in Appendix VI.

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

I. INTRODUCTION

At the request of the Government of Italy, an international team of senior safety experts met representatives of Italian Institute for Environmental Protection and Research, Nuclear Technological and Industrial Risk Department (thereafter refered as ISPRA) from 21 November to 2 December 2016 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Italian regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Italy in January 2012. A preparatory mission was conducted from 2 to 3 March 2016 at ISPRA Headquarters in Rome to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Italy and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS review team consisted of 14 senior regulatory experts from 10 IAEA Member States, 3 IAEA staff members and 1 IAEA administrative assistant. The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, public and environmental exposure control, transport of radioactive material, waste management and decommissioning. The control of medical exposure was out of the scope of the mission. The IRRS review addressed facilities and activities regulated by ISPRA such as radiation sources, research reactors, waste management facilities and nuclear power plants under decommissioning.

In addition, two policy issues were discussed: “Transparency of the Regulatory Body and relation with stakeholders” and “Siting process of disposal facilities and participation of the public”.

ISPRA conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS review team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics within the agreed scope by reviewing the advance reference material, conducting interviews with management and staff from ISPRA, direct observation of working practices during conduct of a regulatory inspection. Meetings were organized with the State Undersecretary of the Ministry of Environment, Land and Sea Protection and other representatives of the same Ministry. Additional meetings were organized with representatives of the Ministry of Economic Development, the Ministry of Labour and Social Affairs, the Ministry of Interior and the Ministry of Health. Meetings with representatives of the Prefecture of Rome, of the National Civil Protection Department, of the Piedmont Region and of the Environmental Protection Agency of this region also took place.

The mission included observations of regulatory activities, interviews and discussions with staff of ISPRA. Activities included visits to the Nucleco waste management facility and the TRIGA RC-1 research reactor in Casaccia, to the Gemelli Hospital in Rome and to the Garigliano nuclear power plant under decommissioning. The IRRS team members observed regulated activities and the performance of inspection activities, and also held discussions with the licensee personnel and management.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Italy's radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards, to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated by ISPRA. The control of medical exposure, regulated by the Ministry of Health, was out of the scope of the review. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS mission will facilitate regulatory improvements in Italy and other Member States, from the knowledge gained and experiences shared between ISPRA and IRRS reviewers and throug the evaluation of the Italy regulatory framework for nuclear safety, including its good practices.

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 Review 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; and

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Italy, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 2 to 3 March 2016. The preparatory meeting was carried out by the appointed Team Leader Mr Ingemar Lund, Deputy Team Leader Mr Patrice Francois, and the IRRS IAEA Team representatives, Mr Ahmad Al Khatibeh and Mr Stewart Magruder.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of ISPRA represented by Mr Lamberto Matteocci, other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities 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;
- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Occupational radiation protection;
- Public and environmental exposure control;

Mr Lamberto Matteocci made presentations on the national context, the current status of ISPRA 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 Italy in November 2016.

The proposed composition of the IRRS team was discussed and tentatively confirmed. Logistics including meeting and work places, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The Liaison Officer for the IRRS mission was confirmed as Mr Lamberto Matteocci.

Italy provided IAEA with the advance reference material (ARM) for the review at the end of October 2016. In preparation for the mission, the IAEA review 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 Codes of Conduct on the Safety and Security of Radioactive Sources and Research Reactors 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

The initial IRRS Review team meeting took place on Sunday, 20 November, 2016 in Rome, directed by the IRRS Team Leader and the IRRS Team 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 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 was present at the initial IRRS Review team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 21 November, 2016, with the participation of ISPRA's senior management and staff. Opening remarks were made by Mr Stefano Laporta, Director General of ISPRA, Mr Ingemar Lund, IRRS Team Leader and Ms Vasiliki Kamenopoulou, IRRS Team Coordinator. Mr Lamberto Matteocci gave an overview of ISPRA activities.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Italy with recommendations and suggestions for improvement and where appropriate, identifying 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 performed its review according to the mission programme given in Appendix IV.

The IRRS exit meeting was held on Friday, 2 December, 2016. The opening remarks at the exit meeting were presented by Mr Lamberto Matteocci and were followed by the presentation of the results of the mission by the IRRS Team Leader, Mr Ingemar Lund. Closing remarks were made by Mr Stefano Laporta, ISPRA Director General and by Mr Peter Johnston Director, Division of Radiation, Transport and Waste Safety IAEA.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Since the early 60's the Italian government has developed a radiation protection and nuclear safety framework aimed at the protection of humans and the environment against the risks of radiation. This framework is set out in several rules and provisions as part of the legal framework that encompasses the protection against ionizing radiation, nuclear safety and management of radioactive waste and spent fuel. The framework also extends to the transport of radioactive materials, fuels and ores, the response to radiation incidents, decommissioning, nuclear safeguards and the security of radioactive sources and nuclear facilities.

In fact, Italy started having a nuclear programme with the construction of 4 NPPs and some fuel cycle research facilities. One additional NPP was under construction in the '80s and others were planned. However, following the referendum of 1987, which took place in the aftermath of the Chernobyl accident, the decision was taken to stop the nuclear programme and to definitively shutdown the operating installations.

The national policy for safety continued to evolve according to the national circumstances. On the bases of the result of a referendum held on 2011, a few months after the Fukushima Dai-ichi accident, the government took the decision to stop the new programme launched in 2009 to reopen the nuclear option. As a result, the current Italian national policy towards nuclear activities is focused on the decommissioning of shut down nuclear installations and to spent fuel and waste management, with provisions and activities related to the siting and construction of a National Repository composed of a near surface disposal facility for L-ILW radioactive waste and a long term storage facility for long lived ILW and HLW.

Various institutions are involved in the regulatory control for nuclear and radiological safety in Italy. First and foremost in the deliberation of regulatory functions are, the Ministry of Economic Development and ISPRA. In addition, the following institutions have been attributed particular competences: Ministry of Health, Ministry of Environment, Land and Sea Protection, Ministry of Labour and Social Affairs, Ministry of Interior, Ministry of Infrastructure and Transport, Ministry of Foreign Affairs, Ministry of Education, University and Research, Ministry of Justice, Department of Civil Protection of the Presidency of Ministry Council, State-Regions Joint Conference, Italian National Institute of Health (ISS), National Institute for Insurance against Accidents at Work (INAIL). The responsibility and functions of any competent authority in a particular area (e.g. radiation protection of workers and public, emergency planning at nuclear installations, off-site emergency preparedness and response) are defined with several specific provisions in the Act No. 1860/1962 and in the Legislative Decree No. 230/1995. In some areas, such as for the control of radiations sources used for medical purposes, the latter one provides only the basis for regional laws that shall define the relevant competent authorities in the regions and autonomous provinces, as highlighted in Section 5.4.

Italy being a member of the European Union, its national legislation is continuously updated as result of transposition of EC Directives.

A National Programme document on the safe management of spent fuel and radioactive waste has been prepared and will be issued after the conclusion of the Strategic Environmental Assessment and taking into account the advice of the competent regulatory Authority and of other Administrations.

With respect to safety culture, the Italian legislation does not establish specific provisions for the promotion of safety culture among the regulatory body and the authorized parties. The

IRRS team was informed that safety culture, even if is not directly addressed in ISPRA's organizational documents, the related principle is applied in all the activities carried out, taking into account the international safety standards and national nuclear safety and radiation protection legislation.

With regard to a national policy and strategy for safety, the IRRS team observed that there are numerous legislative and policy documents with respect to nuclear safety and radiation protection in Italy. However, the IRRS team noted that there is no complete overarching and comprehensive national policy and strategy for safety. In addition, the IRRS team believes that the need and provisions for human and financial resources, the promotion of leadership and management for safety, including safety culture, should be addressed in that comprehensive policy document.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team observed that there are numerous policy documents with respect to nuclear safety and radiation protection in Italy. However, the IRRS team noted that this aspect does not manifest a clear and comprehensive national policy and strategy for safety. In addition, the IRRS team finds that provisions for human and financial resources, the promotion of leadership and management for safety, including safety culture, should be addressed in the national policy and strategy for safety.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 1 para 2.3 para states that** *"National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the Government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:* *(d) The need and provision for human and financial resources;* *(g) The promotion of leadership and management for safety, including safety culture."*
R1	**Recommendation: The Government should continue its efforts to develop a national policy and strategy for safety and include provisions for human and financial resources, the promotion of leadership and management for safety, including safety culture.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The current Italian legislative and regulatory framework related to nuclear safety and radiation protection is the result of an evolution of rules and provisions that began in the early sixties.

The Italian regulatory system is made up of three types of rules of different legal power depending on their origin: legislation, which are acts; legislative decrees and governmental or ministerial decrees; technical guides and technical standards. In the Italian regulatory system the source of legally binding rules must be either an act of Parliament or a legislative decree issued by the Government thus empowered by Parliament. The Government can also issue governmental or ministerial decrees binding in law. The practice of laying down numerical limits and minute regulations in decrees issued by the Executive is very frequent in particular areas relative to radiation protection. An important feature of legally binding rules concerning

nuclear safety and radiation protection in Italy is that contravention to obligations by operators and/or users constitutes a misdemeanour and entails a penal sanction; compliance can be enforced by means of criminal proceedings after due process of law. Legislative Decree No. 230/95, is the main legislative act regulating the regulatory activities. Provisions contained in the current Italian legislation consider exemption, notification or authorization.

The issuing of technical guides is at present assigned by law to ISPRA, which is the regulatory body in Italy, by article 153 of the Legislative Decree No. 230/1995. Technical guides set up technical criteria to be taken into account by operators in the siting of nuclear installations, the authorization or licensing process and the conduct of operations. The compliance with Technical Guides is assessed during the licensing process and ISPRA's inspection activities but they are only binding if referenced in the licence.

Nuclear installations are subject to the ad hoc authorization laid down in the art. n. 6, 7, 10 of the Act No. 1860/1962 and in Chapter VII of the Legislative Decree No. 230/1995. The authorization processes of the more important installations including decommissioning are conducted by the Ministry of Economic Development which issues authorizations acting in accordance with other competent Ministries (Ministries of Environment, Interior, Labour, Health) and the Region concerned; the advice of ISPRA is sought under law in order to determine technical specifications applicable to the installation. The same process is implemented to issue the authorizations for the use of radiation sources of category A (higher level of associated risk, according the categorization defined in the Legislative Decree No. 230/95). Regarding the category B sources, for smaller industrial and research installations the Prefect of the Province has the administrative competence to issue authorizations after seeking the advice of regional technical bodies and of the Fire Corps; the authorization required for most medical installations is issued by the authorities identified by the regional legislation.

The decommissioning of a nuclear installation is based on the binding technical advice of ISPRA. Such advice includes technical specifications as part of the authorization to the decommissioning and takes into account observations expressed by different involved Ministries as well as the Region concerned and, in some cases, the local municipality. Furthermore, any specific management and storage activity of radioactive waste will require, on the bases of a specific decommissioning licence conditions, the approval by ISPRA. The decommissioning authorization can be issued for intermediate phases leading up to a planned final state. This possible subdivision into intermediate phases must be shown to be part of an overall decommissioning plan, to be submitted with the application for the authorization concerning the first phase. Decommissioning operations are carried out under ISPRA regulatory control; at the end of the decommissioning operations the licence holder shall transmit to ISPRA an assessment of the conducted operations and on the state of the site and of the environment. Section 5.5 contains observations on the practical implementation of those legal provisions.

With regard to the regulatory inspection function, according to article 10 of the Legislative Decree No. 230/1995, inspections are performed by ISPRA inspectors having the authority to enter any area of nuclear facilities or radiation facilities or facilities with activities involving natural radionuclides, as well as to have access to any relevant documentation. ISPRA inspection powers are related to nuclear safety as well as radiation protection of workers and the population. In the fulfilment of their duties ISPRA inspectors are vested with police powers, according to which they have power of seizure on installations licence holders deemed to be non-compliant with relevant provisions laid down in the law and in the authorization acts. In case of infringement of specific rules of the nuclear act and licence conditions, including technical specifications, ISPRA inspectors have the obligation to report

to the public attorney. Regarding the inspection, in addition to ISPRA other authorities are vested with inspection competences. In particular, the Ministry of Labour and Social Policy, through its local Labour Inspectorates, has inspection power for the protection of workers from ionizing radiation. The Ministry of Health, through its local Health Bodies, is competent for inspection activities related in general to the protection of the public, and to the protection of workers for medical uses of radiation sources. The Regional Agencies for Environmental protection are competent for inspection activities on working activities involving natural radionuclides (NORM).

The IRRS team observed that there is no comprehensive national plan or policy for maintaining and acquiring the necessary competence for nuclear safety and radiation protection in Italy. Nor are there any specific provisions in the Italian legislative framework indicating the means, activities and processes in relation to this issue. At the time of the IRRS mission there is no explicit national policy and corresponding strategy for safety that would include provisions for necessary professional training to maintain the competence of a sufficient number of suitably qualified and experienced staff for all parties having responsibilities in relation to safety. The same applies for the area of research and development for safety that at present take place only occasionally. Thus, the IRRS team concluded that the Government should make provisions to ensure the necessary professional education and training for further building and for maintaining the competence of a sufficient number of suitably qualified and experienced experts in the area of nuclear and radiation safety. The issue is addressed in Recommendation R2 below. These experts are needed to increase resilience and strengthen the future human resources needs, especially within the regulatory authority.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The provisions for acquiring and maintaining the necessary competence for ensuring safety within the Italian legal and regulatory framework for safety are not complete and not included in a national policy and strategy.	
(1)	**BASIS: GSR Part 1 Requirement 2, para. 2.5 (15) states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *(15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;"*
R2	**Recommendation: The Government should elaborate on the national policy and strategy for developing and maintaining the necessary competence nationally for ensuring safety.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Italian Regulatory Body is a system made of by the Minister of Economic Development, which issues authorizations having force of law and by ISPRA that is the competent regulatory authority for technical regulation, assessment and oversight on nuclear safety and radiation protection of nuclear installations and activities involving the use of radiation sources. The Minister of Economic Development grants the authorizations (i.e. operation license, decommissioning authorization, radiation sources authorizations, etc.), establishing

conditions and technical specifications defined by the Nuclear, Technological and Industrial Risk Department of ISPRA, which supervises their compliance by the authorized parties. Other administrations are also involved in the licensing process to provide their opinion. The main functions of the regulatory body were in the past entrusted to various other institutions. Now, ISPRA is discharging the main functions of a national competent regulatory authority.

ISPRA is a scientific institution, with legal personality under public law and with technical scientific, organizational, financial, managerial and accounting independence. ISPRA is subject to the supervision of the Minister of Environment, Land and Sea Protection. ISPRA is formally separated from other bodies or organizations concerned with the promotion or utilization of nuclear energy, as well as radioactive waste and spent fuel management activities. ISPRA is independent in its safety related decision-making and there is a functional separation from entities having responsibilities or interest that could unduly influence its decision-making. Thus, ISPRA performs its regulatory functions in a functionally independent manner from the Minister of Economic Development. The Institute's budget is funded primarily by the State. Moreover, any approval of specific safety related technical designs and operations are performed by ISPRA, which may establish technical specifications. ISPRA has the legal authority to require the authorized party any information it deems necessary or to perform inspections at its premises and at the premises of suppliers.

The regulatory body will be under a re-organization process: A new competent regulatory authority in the field of nuclear safety and radiation protection, named National Inspectorate for Nuclear Safety and Radiation Protection (ISIN) was established by the Legislative Decree No. 45/2014. According to the same Decree, until the entry into force of ISIN, the functions of the competent regulatory authority shall continue to be carried out by ISPRA. Further, the IRRS team was informed that the Italian Government had just officially completed the procedure to nominate the Director and the members of the Advisory Board of the new Inspectorate according to Legislative Decree No. 45/2014.

The IRRS team was informed that with the establishment of ISIN, actions are expected to be taken to increase the human resources of the competent regulatory authority, also to ensure the necessary turnover of ISPRA's staff members close to retirement. The Decree provides for an increase of the human resources up to 60 technical experts, as well as the possibility to have access to the technical support of external independent bodies. Although the IRRS team welcomes those objectives, it concentrated its review on the existing situation, not taking into account possible probable near future improvements.

The IRRS team observed that the necessary resources and competences are clearly insufficient in several areas of ISPRA's task. Additionally, more than a fourth of the staff will retire within the coming 5 years. This shortage of human resources is visible in all areas, including regulatory control of facilities and activities, regulations and guides development and updates, preservation of knowledge, development and maintenance of the management system, and basic and refreshment training. The IRRS team considers that there is a need to increase the human resources commensurate to all the regulatory functions and the inventory of facilities and activities, also with the view to manage retirement and turn-over of the staff.

The lack of a sufficient number of competent staff has been brought to the attention of the Government and of the Parliament as noted in the Action Plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team noted that ISPRA does not have sufficient number of competent staff to discharge its regulatory functions for all facilities and activities, especially for decommissioning, radioactive waste management and radiation sources.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 4, para 2.8 states that** *"To be effectively independent from undue influences on its decision making, the regulatory body:* *(a) Shall have sufficient authority and sufficient competent staff;"*
R3	**Recommendation: The Government should provide the regulatory body with sufficient competent staff for the proper and timely implementation of its assigned responsibilities.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

According to Act No. 1860/1962 and the Presidential Decree No. 519/1975, the primary responsibility for safety is assigned to the licence holder. This principle has been strengthened by Article 1 of the Legislative Decree No. 185/2011, which transposed the EC Directive on nuclear safety into the national legislation by amending the Legislative Decree n. 230/1995. The licence holder is responsible of all the activities having direct influence on safety performed during design, construction, commissioning, and operation as well as of all the activities performed during decommissioning and management of spent fuel and radioactive waste. The regulatory system in place also ensures that appropriate supervision activity is exploited by ISPRA to verify that the licence holder properly meets its responsibility.

Authorizations are granted to specific persons or organizations that are attributed the exclusive responsibility. In case of activities carried out by several people or organizations they operate under the responsibility of the holder of the authorization. The authorizations cannot be modified by agreements between the parties. The transfer of an authorization can only happen through a new authorization being granted to the new entity or through a specific communication by the licensing authority.

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

In addition to the Ministry of Economic Development and to ISPRA there are other authorities having responsibility for safety and radiation protection (see Section 1.1).

The IRRS team found that specific provisions are established in the Italian legislation addressed to the coordination between involved authorities in respect to their competences. The responsibility and functions of any competent authority in a particular area are defined with several specific provisions in the Act No. 1860/1962 and in the Legislative Decree No. 230/1995.

The IRRS team was informed that the Ministry of Economic Development ensures the necessary coordination, also in case of conflicts in the views of the different other administration. In case of potential inconsistencies among conditions formulated by different authorities the legislative system envisages the possibility for the licensing authority to perform a coordination action trough a so called "Conference of Services".

However, as some responsibilities, i.e. inspection on occupational radiation protection and health care and protection of patients, are shared with other authorities, or remain outside of ISPRA, (i.e. health care and protection of patients), the need for communication and coordination between the authorities is a challenge. For example when a common inspection is performed, the IRRS team was informed that the various results of the authorities involved are not always shared, nor commonly discussed nor agreed upon by consensus. As a result, the IRRS team observed that the coordination among the relevant authorities is not implemented effectively, especially in the field of common inspections. Coordination, cooperation and communication between licensing and supervision activities on all levels should be encouraged by the Government, to assist in achieving consistency, to avoid duplication of inspections done by different authorities and in enabling authorities to agree on common inspection results. The issue is addressed in Suggestion S1 below.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Within the legal and regulatory framework for safety, several authorities are involved. Although some of the regulatory functions of these authorities are specified in the legislation, the IRRS team observed that their coordination is not effective in some cases. This is especially the case during the execution of common inspections and in the cooperation with local and regional authorities in the control of radiation sources, occupational exposure and transport.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 7, para 2.18 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 22 states that** *"The regulatory body shall ensure that regulatory control is stable and consistent."*
S1	**Suggestion: The Government and regulatory body should consider revising existing provisions to ensure more effective coordination of the regulatory functions where appropriate.**

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

The system for protective actions to reduce existing or unregulated radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events is established in the Italian legally binding framework for safety. In particular, specific provisions are also established in the Legislative Decree No. 230/1995, in Act No. 421 of 8th August 1996 and a ministerial decree, with a view to setting up detection apparatus measurement at the borders and at foundries or at facilities collecting metal scrap and recycling plants. The IRRS team was informed that in many instances apparatus and/or surveillance procedures are already in place.

With regard to orphan sources, additional specific provisions are laid down to deal with various issues, such as dealing with radiological emergencies due to orphan sources; drawing

up appropriate intervention plans; and identifying the competent authority responsible for intervention as well as other organizations involved and relative duties.

The IRRS team noted that in a few events connected with the discovery of orphan sources, whose burdens were assigned by the legislation, financial resources were not available for the timing of the safety operations to recover the concerned source. Thus, the IRRS team concluded that more effective funding mechanisms have to be identified for the costs associated to the recovery and management of orphan sources.

This observation was also highlighted by the Counterpart in the preliminary Action Plan for Italy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team was informed that in a few events connected with the discovery of orphan sources, mechanism to ensure financial resources were not available in advance for the prompt recovery and management of these sources.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 9 states that** *"The Government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 9 para 2.25 states that** *"The organization taking the protective action shall have access to the resources necessary to fulfil its function."*
R4	**Recommendation: The Government should make provisions to ensure that organizations taking protective actions to recover and manage orphan sources have access to the necessary funding to fulfil their functions.**

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

The current national decommissioning policy was established in 2004. As indicated in Section 1.1, the National Programme for the management of spent fuel and radioactive waste from generation to disposal is under approval and the Strategic Environmental Assessment is on-going. The decommissioning of the nuclear installations and the associated spent fuel and radioactive waste is managed since 1999 by SOGIN (Società Gestione Impianti Nucleari) S.p.A. SOGIN operates under strategic and operational guidelines provided by the Italian Government. It is the national implementer responsible for performing decommissioning and waste management activities for all Italian nuclear installations.

The Italian legal framework addresses the requirements related to decommissioning and management of radioactive waste in Legislative Decree No. 230/1995 and Legislative Decree 45/2014. Since the beginning of its nuclear programme, Italy has pursued the option of reprocessing abroad the spent fuel produced in its NPPs.

As far as the financial resources for decommissioning are concerned, the National Electricity Company (ENEL S.p.A.) decided to start accumulating decommissioning funds during the NPPs operation. When in 1999 all the liabilities and assets related to nuclear power plants

were transferred to SO.G.I.N. new funding mechanisms were identified to finance the full decommissioning costs. Since January 2000, the financial resources are provided by a levy on the price of the kWh of electricity to the consumers in combination with the pre-existing funds that were transferred.

The decommissioning of a nuclear installation is subject to prior authorization by the Ministry of Economic Development in accordance with the Ministry of Environment, Land and Sea Protection, the Ministry of Interior, of the Ministry of Labour and Social Policy, Ministry of Health, the Region concerned and the competent regulatory Authority. The decommissioning licences for Trino and Garigliano NPPs have been issued in 2012 and for the Caorso NPP in February 2014.

The IRRS team was informed that the Italian legislation regulates the decommissioning of nuclear installations as a comprehensive set of actions where authorizations can be granted for subsequent phases leading up to planned and definite intermediate states. Such a possibility, however, is recognised on condition that the proposed subdivision into phases is shown to be part of an overall decommissioning plan leading up to a final site unconditional release and defining, inter alia, the destination of resulting radioactive materials. In addition, the national legislation requires that the decommissioning plans can be authorized only in presence of the results of the environmental impact assessment. Furthermore, the experience resulting from the management of nuclear installations permanently shut down since many years, clearly indicates some other priorities before starting the bulk of the dismantling activities.

As stated above, the IRRS team was informed that, a National Programme document on the safe management of spent fuel and radioactive waste has been prepared and will be issued after the conclusion of the Strategic Environmental Assessment and taking into account the advice of the competent regulatory Authority and of other Administrations. This document is intended to contain all the elements of the national strategy for the management of radioactive waste. After the issue of the document, a periodic review and update is envisaged by the legislation.

However, the IRRS team observed that currently the national strategy for the management of radioactive waste is not yet comprehensive. In particular, there is no clearly stated national policy for the disposal of Long-Lived Intermediate-Level Wastes (ILW) or High-Level Waste (HLW). Arrangements for the disposal of radioactive wastes other than those coming from decommissioning by SOGIN of the NPPs and fuel cycle facilities, at the National Waste Repository are yet to be established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Some elements of a national policy and strategy for decommissioning and radioactive waste management, including disposal, are established in different legal documents. However, a comprehensive, coherent and consistent policy and strategy on decommissioning and management of radioactive waste, including disposal, is not yet established.	
(1)	**BASIS: GSR Part 1(Rev.1) Requirement 1 states that** *"The Government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 10, para 2.28 states that** *"Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of Governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities. The strategy shall include appropriate interim targets and end states."*
(3)	**BASIS: GSR Part 5 Requirement 2, states that** *"To ensure the effective management and control of radioactive waste, the Government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles and with international instruments, conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste."*
(4)	**BASIS: GSR Part 6 Requirement 4, para 3.2 states that** *"The responsibilities of the Government shall include: - Establishing a national policy for the management of radioactive waste, including radioactive waste generated during decommissioning."*
R5	**Recommendation: The Government should complete its policy and strategy for decommissioning and management of radioactive waste, including disposal.**

1.8. COMPETENCE FOR SAFETY

Since 1962 the Italian legislation required that the applicant for an authorization related to a nuclear installation must demonstrate adequate technical and financial capacity. Italy's legislation sets up specific requirements for the licence holder to provide adequate financial and human resources in order to properly discharge its responsibility for safety. It also establishes specific requirements for the licence holder to maintain and enhance the experience and expertise of its staff that have responsibility in the field of nuclear safety and in the management of spent fuel and radioactive waste, through appropriate training and refresher programs. The licence holder is also required to ensure that staff of third parties, who are contracted to carry out activities that are relevant to nuclear safety and the management of spent fuel and radioactive waste, provide a certificate to have been adequately formed with specific training courses. Current regulation establishes specific qualification requirements for the staff involved in the operation of the nuclear installations. These requirements are also applicable to radioactive waste and spent fuel management facilities which are operated under the licensing conditions of the main nuclear installation they belong to. Additionally, staff qualification for the performance of any safety-related activity is among the relevant aspects assessed during the licensing process.

The IRRS team noted that for the new regulatory authority (ISIN), there is a specific legislative provision to which the competent regulatory Authority ensures the maintenance

and development of skills in the field of nuclear safety and radiation protection of its staff, through appropriate training tools and retraining. The main tool adopted for the young members of the staff is the training on the job in licensing and inspection activities.

The competent regulatory authority also grants to its staff the opportunity to attend, where necessary, specific training programs mainly related to topics relevant to the regulation of decommissioning as well as spent fuel and radioactive waste management.

Moreover, staff qualification for the performance of any safety-related activity is among the relevant aspects that are assessed during the licensing process. In nuclear installations, only licensed personnel can operate. In such installations, the Operating Rules ("Regolamento di esercizio") required by the Italian legislation, establish requirements about the organization and the roles of the technical and operating staff, to ensure a safe management of the installation (even regarding the activities related to waste management and dismantling operations) in ordinary and emergency conditions.

The IRRS team observed that for the Nuclear, Technological and Industrial Risk Department of ISPRA the recruitment of new personnel to ensure the continuity and the effectiveness of regulatory functions in the next future is an issue to be monitored. This is especially due to the upcoming personnel retirements and the expected significant increase of regulatory activities at the national level on spent fuel and radioactive waste management and decommissioning, including the siting and construction of a National Repository, as well as to nuclear safety related activities required by a new regional and international context followed to the Fukushima Daiichi accident and to the strengthening of regulatory control on radiation sources. ISPRA has presented this issue to the Parliament and to the Government (see Sections 1.2 and 1.3).

In relation to research and development activities, during the past operation of the NPPs, with a larger number of human resources present, research and development activities were followed in a continuously and structured manner through dedicated organizational structures. The IRRS team noted however that at present, given the progressive reduction of human resources, these activities now only take place occasionally. The government provided for the establishment of research centres (CNEN then ENEA), which, together with a few Universities, was devoted to development and practical applications in the areas of nuclear research and safety. With the change in the national nuclear policy after the two referendum on the use of nuclear energy the main duties of ENEA changed. Nuclear activities have been maintained, but they are not anymore the main activities of these organizations. The IAEA team encourages the participation of ISPRA and operating organizations in relevant research and development activities and in particular in those related to the disposal of radioactive waste.

1.9. PROVISION OF TECHNICAL SERVICES

The Italian regulatory framework includes various provisions for dosimetry services for monitoring equipment and the calibration of such equipment. A few provisions are also addressed to the recognition of these technical services. The procedures for the qualification of the various institutions are regulated by a Ministerial Decree of the Minister of Labour and Social Affairs, in consultation with other Ministers and administrations among which also the Nuclear, Technological and Industrial Risk Department of ISPRA. Dose evaluations or activities should be carried out by means of measurements which are provided with calibration certificates. The criteria and procedures for issuing calibration certificates are established in accordance with the provisions laid down in an Act of 1991. Dosimetry Services who carry out service activities of personal dosimetry are subject to the supervision

of ISPRA and, for this purpose, have to communicate, within thirty days, when the beginning of the activities took place.

The IRRS team noted that the Government has made provisions for technical services in relation to safety, such as services for personal dosimetry and the calibration of equipment. However, the IRRS team was informed that the provisions regarding the qualification of these technical services as well as the definition of the competent authority responsible for the authorization or approval of such services are regulated by a Ministerial Decree that has not been enacted yet. However, the IRRS team was informed that the criteria and procedures for authorization of the dosimetry services are going to be included in the new regulation derived of the transposition of the new European Directive 59/2013.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team observed that provisions for the qualification and approval of technical services such as for personal dosimetry and calibration of equipment have not been enacted.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 13 states that** *"The Government shall make provisions, where necessary, for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment."*
(2)	**BASIS: GSR Part 1(Rev.1) Requirement 13, para 2.41 states that** *"The regulatory body shall authorize technical services that may have significance for safety, as appropriate.*"
R6	**Recommendation: The Government should enact implementation provisions to ensure that technical services with significance for safety are qualified and authorized.**

1.10. SUMMARY

The IRRS team observed that there are numerous policy documents with respect to nuclear safety and radiation protection in Italy. However, the IRRS team noted that this aspect does not manifest a clear and comprehensive national policy and strategy for safety and is lacking provisions for human and financial resources and for the promotion of leadership and management for safety, including safety culture. A comprehensive, coherent and consistent policy and strategy on decommissioning and management of radioactive waste, including disposal, is not yet established. The Government should continue its efforts on developing such policies and strategies.

Within the Italian legal and regulatory framework for safety there is no national policy and strategy for acquiring and maintaining the necessary competence nationally for ensuring safety. ISPRA, the main regulatory authority in Italy, has no sufficient competent staff for the proper and timely implementation of its assigned responsibilities. The Government should provide the regulatory body with sufficient competent staff for the proper and timely implementation of its assigned responsibilities.

Several authorities are involved within the legal and regulatory framework for safety, but, in some cases, the coordination amongst them is not effective. The Government and the regulatory body should enhance this coordination.

In a few events connected with the discovery of orphan sources, financial resources were not sufficient for the prompt recovery and management of these sources. The Government should therefore make provisions to ensure that organizations taking protective actions to recover and manage orphan sources have access in advance to the necessary funding to fulfil their functions.

Finally, the Government should complete the legal framework for the recognition of technical services, such as personal dosimetry and equipment calibration, and for the establishment of national data bases related to safety.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Italy is a Contracting Party to all relevant international conventions that establish common obligations and mechanisms for ensuring protection and safety: the Convention on Nuclear Safety (CNS), the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (JC), the Paris Convention on Nuclear Third Party Liability and the Brussels Supplementary Convention, and related protocols, the Treaty on the Non-Proliferation of Nuclear Weapons (NPT), the Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency, the Convention on Early Notification of a Nuclear Accident, the OSPAR Convention and the Convention on the Physical Protection of Nuclear Material (CPPNM) including its Amendment.

The Italian Government has committed itself to both the Code of Conduct on the Safety and the Security of Radioactive Sources and the Code of Conduct for Research Reactors. Still, the political commitment to the Technical Guidance on Import and Export of Radioactive Sources for the Code of Conduct on the Safety and the Security of Radioactive Sources is missing. Italy is also represented at the periodical review meetings of the CNS and the JC. Italy actively participates in the IAEA safety standards committees and most of the IAEA safety standards for NPPs have been transposed into Italy's nuclear legislation. Italy further participates in several international organizations (e.g. OECD/NEA, ENSREG, HERCA, WENRA) and their related working groups and specific committees.

In addition, ISPRA has strong bilateral cooperation with various countries, amongst these France, Romania, Slovenia, Switzerland, Ukraine, and the United States of America (U.S.A.).

International (IAEA) review-missions are an integral part of the supervision-strategy of ISPRA. Examples are OSART Missions (1987, 1988, 1989). ISPRA personnel have continuously participated in IRRS missions such as in Slovenia, in the USA, in Switzerland, in the Czech Republic and in Bulgaria.

The IRRS team acknowledged that ISPRA is an active member of WENRA and has actively participated in the establishing of safety reference levels as basis for the harmonization of the regulatory framework, both for reactors and for decommissioning and waste management. In developing the Italian nuclear safety legislation and the regulatory guides of ISPRA, the IAEA safety standards as well as the WENRA safety reference levels, are considered when appropriate. In particular, the IRRS team noted that ISPRA has used the outcomes from the work within WENRA for establishing and implementing a national action plan to correspondently update its basic safety regulations, mainly addressing issues related to decommissioning and waste management. In this respect, the IRRS positively noted that ISPRA has voluntarily performed an international review of a technical guide drafted to establish siting criteria of a centralized near surface disposal facility for low and intermediate level radioactive waste in 2012-2013. In addition, technical exchanges on this guide also took place with the nuclear safety authorities of France, Switzerland, Belgium and Slovenia.

The IRRS team acknowledged the active participation of ISPRA to the Working Party of Atomic Question Group of EU Council in relation to the adoption of Euratom Directives. The IRRS team was informed that ISPRA participated in the Stress Test Peer Review exercise requested by the EC in 2012 and hosted a national Seminar on the Fukushima accident open to ONG (Environmental Associations) to share lessons learned with neighbour countries (France, Slovenia, Switzerland and Austria).

The IRRS team concluded that the Italian Government and ISPRA effectively fulfils their international obligations, participate in the relevant international arrangements, including international peer reviews, and actively promote international cooperation to enhance safety globally.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The main features of ISPRA's approach on sharing view and using the operating experience to draw lessons learned feeding its regulatory activity are the following:

- Through bilateral agreements: Sharing operating experience and regulatory practices through the cooperation established in the frame of bilateral Agreements, e.g. by analyzing operating experience on national disposal for the LLW disposal and on the ILW-HLW long term storage with regard to the conceiving and establishing of disposal facility design criteria. What above as experienced through the implementation of the cooperation with ASN, ENSI, SNSA and by site visits with the respective operators.
- At the multilateral level, through participations in the Review Meetings of the CNS and the JC as well as in international conferences and meetings.
- At the regional level through the participation in the WENRA and ENSREG activities, by collaborating in the drafting of new technical guides on safety criteria for interim storage of radioactive waste and spent fuel and on decommissioning of nuclear installations.

The IRRS team was informed that the dissemination and implementation of the lessons learned derived from the operating experience is partially performed, based on ISPRA's provisions for periodic review and continuous increase of the safety of installations and is realized at the nuclear facilities primarily through ISPRA's approval of selected activities following the respective decommissioning license. Such actions consist in the approval of detailed design reports such as related to new on site constructions (e.g. new temporary storage facility), or of plans of operations as related to dismantling activities.

The IRRS team observed that most of the necessary elements of operational and regulatory experience feedback are not in place. In particular, activities related to collecting and analyzing operating and regulatory experience feedback at ISPRA are not deployed in a structured and systematic way in line with international practices. Specific arrangements are not currently in place for a systematic implementation and use of operational and regulatory experience. The IRRS team was informed that a case by case evaluation is however performed following relevant events. Further, the IRRS team observed that the process for the use of lessons learned, operating and regulatory experience is not defined and documented in ISPRA's management system. The IRRS team was informed that a procedure, which details the process for the use of lessons learned, operating and regulatory experience, is under preparation to be included in the management manual.

This observation was also highlighted by the counterpart in the preliminary Action Plan for Italy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulatory body's processes related to operating and regulatory experience feedback are not implemented in a structured and systematic way.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.*
(2)	**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. Such measures could comprise promulgation of new regulatory requirements or making safety enhancing modifications to operating practices or to equipment in authorized facilities and activities. Such feedback provided in response to information received via international networks also covers descriptions of good practices that have been adopted to reduce radiation risks."*
S2	**Suggestion: The regulatory body should consider developing arrangements for identifying, analysing and disseminating lessons learnt from national and international operating and regulatory experience feedback in a more structured and systematic way.**

2.3. SUMMARY

The Italian Government and ISPRA effectively fulfil their international obligations, participate in the relevant international arrangements, including international peer reviews, and actively promote international cooperation to enhance safety globally. However, the IRRS team observed that the regulatory body's arrangements related to operating and regulatory experience feedback and lessons learnt dissemination at ISPRA need to be improved and to be performed in a structured and systematic way.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

In Italy, the key regulatory functions (rulemaking, licensing, assessment, inspection and enforcement) related to nuclear safety and radiation protection matters, related to NPPs (siting, construction, operation and decommissioning) as well as safe management of spent fuel, radioactive waste, and safe application of radiation sources are currently carried out by two main bodies:

- The Ministry of Economic Development, as the Licensing Body, is the authority which grants the licence/authorization for nuclear installations (from the design and construction to the decommissioning). Authorizations are granted on the basis of the technical advice provided by the competent regulatory authority (the Nuclear, Technological and Industrial Risk Department of ISPRA – National Institute for Environmental Protection and Research) and in agreement with the Ministry of Environment, Land and Sea Protection, Ministry of Interior, Ministry of Labour, Ministry of Health and the Region concerned, after the issuing of the environmental compatibility statement by the Ministry of the Environment, Land and Sea Protection, when applicable;
- The Nuclear, Technological and Industrial Risk Department of ISPRA, as the competent regulatory authority, is the competent authority currently responsible for the assessment and the inspection activities on nuclear installations, as well as for approving detailed designs of specific activities, which are part of authorizations granted by the Ministry of Economic Development, for the construction of nuclear facilities and the implementation of their modifications, as well as the implementation of decommissioning projects as established in the decommissioning licence. ISPRA supervises the compliance with the requirements established in the legislation and the conditions and specifications established in the Ministerial authorization decrees throughout its inspection activity. ISPRA is also the competent body entitled to support the Governmental rule-making function in the field of nuclear safety and radiation protection. ISPRA is also entitled to issue technical guides relating to the different operational aspects of the regulatory process. Other duties of ISPRA include supervision activities on safeguards and physical protection, the exploitation of a technical support function in the field of emergency preparedness and of a control function in the field of environmental radioactivity.

In 2014, the Legislative Decree No. 45 established a new competent regulatory authority in the field of nuclear safety and radiation protection, which is the National Inspectorate for Nuclear Safety and Radiation Protection (ISIN), fully dedicated to the regulation and control in the nuclear field. In relation to the structure of ISIN the Legislative Decree n. 45/2014 envisages:

- a Director, nominated with a decree of the President of the Republic, designated by the Council of Ministers based upon the proposal of the Minister of the Environment in agreement with the Minister of Economic Development, and following the positive advice of Parliamentary Commissions;
- an Advisory Board of 3 members, nominated under the same procedure;
- Staff of 60 units of technical personnel, mainly from ISPRA.

ISIN will have regulatory, operational and administrative independence and the possibility to get technical support of third, independent, expert organisations (in particular ISPRA and regional agencies for environmental protection). The new Inspectorate's financial resources will consist of the resources currently allocated to ISPRA, and the resources coming from the fees that ISIN is authorized to apply and collect from the licence holders for the exploitation of its regulatory functions. The IRRS team was informed that the procedure to nominate the Director and the Advisory Committee of the new Inspectorate has been completed by the Government.

In the transition period until the new Inspectorate will become operative, functions and duties of the competent regulatory authority for nuclear safety and radiation protection continue to be performed by ISPRA through the following Divisions:

- Control of Nuclear Activities Division;
- Nuclear Technologies Division (Nuclear engineering section, Radioactive waste management section, Mechanical and civil structure section, Safety analysis office);
- Radiation Protection Division;
- Radiometric Measurements Division.

ISPRA manages its resources according to a graded approach considering the risk associated and the number and type of facilities and activities operated in Italy. Large part of the available resources has been allocated taking into account that most of the activities of assessment, control and inspection are addressed to spent fuel and waste management and nuclear facilities decommissioning. Remaining resources are dedicated to the assessment, control and inspections related to the use of some sources in industrial and medical activities, in transport of radioactive material, in safeguards of nuclear material and in emergency preparedness and response.

At present a total number of 35 technical staff members is assigned to ISPRA. About 40 % of the staff will retire in the coming 5-7 year. At present ISPRA is funded through the State budget with a total annual budget of about 3.5 Million EURO, including cost of personnel.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

ISPRA is an institute reporting to the Ministry of Environment, Land and Sea Protection and is independent from any entity involved in the promotion and use of nuclear energy. Moreover, any approval of specific safety related technical designs and operations are granted by ISPRA, which may establish technical specifications. ISPRA performs the functions of the competent regulatory Authority for nuclear safety and radiation protection by the Nuclear, Technological and Industrial Risk Department. ISPRA is a scientific institution, with legal personality under public law and with technical, scientific, organizational, financial, managerial and accounting independence. ISPRA is functionally separated from the Ministry of Economic Development which is in charge to grant authorizations and its advices are binding for the Ministry. ISPRA is empowered to formulate in its advice conditions and technical specifications to be attached to the authorization.

ISPRA's performed review and assessment, control and inspection activities are based on technical guides and standards. The review and assessment practice exploited to underpin licensing decisions is based on an internal review process conducted by different experts.

The legislative framework and ISPRA's regulation prevents any conflicts of interests by the explicit prohibition both for the institution and employees to conduct activities which are in conflict the institutional duties. With regard to the requirement of ensuring that a clear separation exists between the regulatory body and organizations or bodies charged with responsibilities for the promotion or application of nuclear or radiation related technologies, Article 13 of ISPRA's regulation establishes that activities which are incompatible with its institutional duties are forbidden.

As stated by art. 10 of Legislative Decree 230/95 the inspector has the authority to intervene in any facilities and activities that present significant radiation risks irrespective of the costs to the authorized party. ISPRA inspectors are entitled by law with the authority to access any installation where radiation sources are used or stored and to request any information in order to ascertain compliance with legislative requirements and licence conditions. ISPRA inspectors are entitled by law with the proper authority to request the licensee any information deemed necessary to ascertain compliance with legal requirements and licence conditions. In case of infringements, ISPRA inspectors report to the Public Prosecutor of the jurisdiction the installation belongs to.

In order to ensure that the staff remains focused on safety irrespective of their personal views, the assessment, control and inspection activities are conducted only on the bases of legislative provisions, technical guides and standards, and authorizations conditions and technical specifications. In relation to the formulation of advices related to the licensing process the decision making process is carried out involving different experts with the final approval of the responsible division head.

To maintain the independence in the very limited cases in which new staff is recruited from the organization involved in nuclear and radiation related activities, these persons are not assigned to roles in which they might compromise the independence of the regulatory body. They are on the job trained on regulatory culture and on the first phase they operate under the tutoring of the existing staff. The IRRS team was informed that if a new person is recruited from the regulated industry, this person does not take part in the oversight of the activities of his or her previous organization.

The IRRS team therefore concluded that ISPRA as a regulatory body performs its functions in a manner that does not compromise its independence and meets the safety requirements of the IAEA on effective independence.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The present number of the technical staff members assigned to t ISPRA counts 35 professionals. About 40 % of the staff will retire in the coming 5-7 years. The Italian regulatory framework gives a wide range of responsibilities to ISPRA that require appropriate human and financial resources to ensure adequate and effective regulatory control of safety. The IRRS team was informed that it is more and more difficult to recruit nuclear safety experts with adequate knowledge.

The IRRS team was informed that the planning of the resources of ISPRA is based on a strategy plan and the annual planning of the activities. Further, the IRRS team was informed that the training needs at ISPRA are assessed in the annual evaluation of the employees and an annual training plan is developed accordingly. For the nuclear safety training, the services provided by the IAEA are widely used. However, the IRRS team observed that there is no formal periodic, systematic assessment of the training needs. In addition a documented view of the resources and competences needed, taking into account the development of the current and

future use of radiation sources and their oversight, is not developed yet. Further, the IRRS team observed that several areas of ISPRA's responsibilities rely on a single expert in the organization e.g., electro-technical, chemical, civil engineering; e.g. ISPRA indicated to the IRRS team that no expert on hydrogeological and geological aspects is available and that support may be provided by experts from other ISPRA Departments. The IRRS team therefore noted that the necessary competences are insufficient in several areas of ISPRA's task, in particular in the area in processes such as regulatory control of facilities and activities, regulations and guides development and updates, preservation of knowledge, development and maintenance of the management system, and basic and refreshment training. In addition, not sufficient number of specific competence and expertise is present in the field of disposal. As a result, in the view of the IRRS team the redundancy/capacity of expertise, the ageing of staff and the future needs of ISPRA's oversight activities should be considered in the resource and competence planning in a timely manner. The IRRS team therefore concluded that a systematic formalized approach should be developed for managing ISPRA's nuclear resources and competences, so that the delivery of ISPRA's statutory responsibilities in the long term can be ensured.

This observation was also highlighted by the counterpart in the preliminary Action Plan for the IRRS Mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team observed that a long term strategy for human resources development is not in place in particular to compensate for the departure of qualified staff. The IRRS team was informed that the regulatory body has not a sufficient number of competent resources and expertise in some fields, such as licensing of disposal facilities. Furthermore, the re-training process of the current staff is limited.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 18 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."*
(2)	**BASIS: GSR Part 1(Rev.1) Requirement 18 para 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."*
(3)	**BASIS: SSR-5 para 3.9 states that** *"The regulatory body has to maintain competent staff, to acquire capabilities for independent assessment and to undertake international cooperation, as necessary, to fulfil its regulatory functions."*
R7	**Recommendation: The regulatory body should establish a process for**

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	developing and maintaining the necessary competences and skills of its staff.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The Italian legislative framework for radiological and nuclear safety does not include provisions for the establishment of an advisory body to the competent regulatory authority in relation to its responsibilities and authority. The IRRS team was informed that the policy of the competent regulatory Authority in Italy has always included the use of its own experts for safety assessment activities.

For NPPs and fuel cycle facilities, generalists are in charge of follow-up activities of nuclear installations and are supported by a pool of specialists on specific topics (civil engineering, accident analysis, fire safety, waste, radiation protection). A set of competencies and skills are missing already at ISPRA such as specialist on human and organizational factors and quality management systems of the operators, covered however by other experts of the Department. No external experts are assigned to support ISPRA activities due mainly to the lack of financial resources to contract external experts.

At the time of the IRRS mission, ISPRA has no advisory body and is not using support organizations for obtaining technical or other expert professional advice or services in support of its regulatory functions. Only specific agreements are in place with Environmental Protection Agencies of regions which host nuclear facilities to perform monitoring of environmental radioactivity and independent measurements of discharges to support ISPRA's oversight activity.

For the future, the Legislative Decree 45/2014 envisages for the new independent regulatory authority ISIN the possibility to obtain technical support from ISPRA, environmental protection agencies and other entities fully independent from the authorized parties not involved in the promotion and management of activities in the nuclear field. This observation was also highlighted by the counterpart in the preliminary Action Plan for Italy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ISPRA has no advisory body and cannot use support organizations to obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, because it does not have the needed financial resources for obtaining external professional advice when this cannot be handled by ISPRA staff. The IRRS team has been informed that support is however provided by ARPA in discharges control and environmental monitoring through specific arrangements.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 20 states that** *"The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 20, para 4.18 states that** *"The regulatory body may decide to give formal status to the processes by which it is provided with expert opinion and advice. If the establishment of advisory bodies, whether on a temporary or a permanent basis, is considered necessary, it is essential that such bodies provide independent advice, whether technical or non-*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	technical in nature."
(3)	**BASIS: GSR Part 5 Requirement 3, para 3.10 states that** *"To fulfil its regulatory functions, the regulatory body, where appropriate, may undertake research, acquire independent assessment capabilities and participate in activities for international cooperation."*
R8	**Recommendation: The regulatory body should obtain technical or other expert professional advice as necessary in support of its regulatory functions provided that adequate financial resources are made available.**

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

ISPRA has established mechanisms of communication with authorized parties, either at formal or informal levels, in order to justify and explain regulatory decisions as necessary, and conduct a professional and constructive liaison. At a formal level, during the licensing process any request of clarification or additional information related to the application documents is formally communicated. Technical meetings are also held during the implementation of the licensing procedure. Further, technical specifications and conditions to be attached to authorizations are normally communicated in advance to the authorized party so that they can understand their basis and their aims. Informal meetings are also arranged for presentations and discussions of licensee proposals, new projects or programmes, as well as seminars and workshops.

ISPRA informs applicants and authorized parties of the policies, principles, safety objectives and associated criteria on which regulatory judgements and decisions are based, in compliance with its legislation, which states that the competent regulatory authority takes the necessary actions to make available information on the regulation of nuclear safety and radiation protection to applicants and authorized parties. Tools to inform on safety objectives and criteria are represented by the technical guides issued by ISPRA.

The IRRS team was also informed that there are regular quarterly meetings between ISPRA and the Italian national implementer. A protocol is produced and the information is disseminated within ISPRA. Other liaison means are the use of official letters, meetings with or without recorded minutes (reports). The changes of the regulatory requirements are effectively distributed to all stakeholders. The information on ISPRA's decisions is provided in public hearings and made available on request.

Thus, the IRRS team concluded that clear mechanisms of communication are established between ISPRA and authorized parties, either at a formal or informal level.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The IRRS team was informed that ISPRA ensures that regulatory control is stable and consistent. This is ensured on the basis of the requirements established by the legislative framework in which the processes related to the authorizations, assessment and control are established. ISPRA conducts its core processes on the basis of an established practice experienced for decades and it bases its assessments on the reference levels and technical

requirements as reported in the legislation, in technical guides and in selected international standards.

The IRRS team was informed that procedures are planned to be included in the management manual under preparation. Still, the IRRS team observed that there is no explicit mechanism by which the regulatory body has formally specified the policies, principles and criteria to be observed in the implementation of its core processes (see Module 4).

ISPRA's decision-making process is conducted so that review and assessment activities are objectively performed assuming as reference national and international standards and quantitative objectives. In addition, the results of the performed review and assessment is conducted and reviewed by different experts and they are always internally discussed before a decision is taken. In some cases the regulatory assessment results are not documented in specific reports but summarized in the advice to the licensing authority.

Further, regulatory requirements are changed or adapted by the issuing of further implementation decrees, taking into account technical developments and applicable EC Directives. By means of such Decrees, specific rules for specific situations and activities, including those involving exposure to natural sources of radiation, are also identified in relation to technical developments as well as to EC Directives. The IRRS team also observed that the national framework is updated regularly to reflect any change in the nuclear policy. Recommendations and suggestions for improving the consistency and stability of regulatory control are addressed in specific modules.

3.7. SAFETY RELATED RECORDS

The IRRS team was informed that each authorization is granted with a decree of the licensing body (Ministry of Economic Development) based upon the advice of ISPRA taking into account the views and observations expressed by other involved administrations. The same applies for amendments, suspensions or revocations of licenses. The basis for the decisions is formally recorded in the authorization itself. In addition, for major authorization ISPRA prepares a specific technical report in which the basis of the regulatory decision is reported in more detail.

There are other important records that are maintained by ISPRA such as an inventory of radioactive waste. It is updated every year on the basis of the declarations of authorized parties.

ISPRA has made some provisions for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities. Information on decommissioning of facilities is maintained in the documentation of each facility. In the same way the records of accidents and significant events are maintained related to the facilities and activities authorized. These registers and data bases are used as references to address the regular oversight activity. ISPRA makes use of the safety related records to verify the compliance of the safety requirements by the authorized party and to set priorities for its licensing and inspection activities.

Authorized parties are also obliged in the authorization to keep several records (inventory of sources, of waste, register of discharges etc.) necessary for the safe management of the facility or activity. ISPRA addresses regular oversight activity to ascertain that these records are properly kept.

The Italian legislation (Legislative Decree No. 52/2007) establishes a national register of radiation sources, but the register has not been implemented yet. The IRRS team was informed that the inter-ministerial decree which will implement this procedure and identify the national organization responsible for the management of the national source register is expected to be

issued by in the near future. The scheme of the inter-ministerial decree envisages provisions which define the arrangements for establishing, processing, updating and accessing data and also identify ISIN as the national organization responsible for the management of the national source register. ISPRA has already developed the hardware and the software system for this purpose. Additionally, ISPRA has established the guidelines for the transmission of data on electronic form of information of the sources by the holders.

Related to occupational exposure, Article 76 of the Legislative Decree No. 230/1995 establishes that a national register should be put in place on the basis of a Legislative Decree to be issued by Minister of Labor and Social Affairs together with the Minister of Health. The IRRS team was informed that as a consequence of the publication of the EC Directive 59/2013, the Government will implement the national register in connection with the transposition of EC Directive 59/2013. See Section 11.1 for further information on dose recording.

In addition, the IRRS team noted that a database containing data of transports of radioactive material is also kept based upon the declarations that every three months authorized carriers are obliged to transmit to ISPRA based upon a condition attached to the authorization. The data base of the competent regulatory Authority is used as reference to address the regular oversight activity. The radioactive waste inventory is also used to propose the proportional distribution of compensation measures to the local communities hosting the nuclear installations on the bases of legislative Acts. Authorized parties are obliged in the authorization to keep several records (inventory of sources, of waste, register of discharges etc.). Regular oversight activities are also addressed to ascertain that these records are properly kept.

The IRRS team observed that ISPRA receives information from the main producers of radioactive wastes and from the treatment, conditioning and storage facilities in Italy and compiles this to document a national inventory of radioactive wastes and spent fuel. ISPRA only has the information on institutional radioactive waste that is provided by predisposal management facilities when they are collecting these waste. The information about the currently in place radioactive waste, including disused sealed radioactive sources, in the institutions of category B facilities is not collected by ISPRA and is not considered in the national inventory. ISPRA has taken responsibility for this task even though the responsibility for undertaking this task is not explicitly assigned in the Italian legislation. The maintenance of the national inventory is an important task as it is necessary for planning of the national strategy for waste management and is a key source of information for reporting to international processes such as the Joint Convention. The IRRS team observed that ISPRA is doing a good job of maintaining the national inventory with only limited resources for the task (less than one full time person per year).

The IRRS team has observed that the increase or decrease of doses in the various occupational fields cannot, as the situation is, be quantified. The general effectiveness of optimization in Italy can also not be compared and evaluated. Thus, Italy has no complete and reliable overview over the number of radiation exposed workers and their doses. Complete annual national dose statistics and trends in different work sectors and occupational fields do not exist.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Within the Italian legislative framework specific implementation Decrees are established for national registers of radiation sources and occupational exposures. They have however not been enacted yet.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 35 paragraph 4.63 states that**

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	"The regulatory body shall make provision for establishing and maintaining the following main registers and inventories: - *Registers of sealed radioactive sources and radiation generators* - *Records of doses from occupational exposure."*
(2)	**BASIS: GSR Part 3 Requirement 20, para 3.73 states that** *"The regulatory body shall be responsible, as appropriate, for: (e) Provision for maintaining exposure records and results of the assessment of doses from occupational exposure."*
R9	**Recommendation: The Government should enact the decrees on the establishment of the national register of radiation sources and national records of doses from occupational exposure and the regulatory body should ensure their implementation.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

For nuclear activities, the Legislative Decree No. 230/1995 states that the competent regulatory authority takes the necessary actions to make available to the general public and workers information on the regulation of nuclear safety as well as spent fuel and radioactive waste and provides to publish on its website the results of its performed regulatory activity and all useful information in its fields of competence. The above mentioned article also states that information is made available with the exception of classified ones, having in particular relevance for security. The IRRS team was informed that the regulatory body notifies interested parties and the public of the principles and criteria for safety used as the basis for its regulations and guides, and makes these regulations and guides available. Further, the IRRS was informed that the regulatory body promotes the establishment of appropriate means of informing and consulting interested parties and the public about possible radiation risks associated with facilities and activities and about the processes of the regulatory body.

With regard to the monitoring of environmental radioactivity, these activities and the related results are submitted in the "Annuario dei dati ambientali", the ISPRA open access database of environmental indicators. Regularly, ISPRA publishes the activity report with all activities carried out in nuclear facilities under control that are periodically reviewed to ensure their adequacy and effectiveness and the annually results can be compared.

The IRRS team was informed that periodic communications are prepared in the form of public hearings organized at the local level by the Regions where the nuclear facilities are located. An important mean to provide information is represented by the participation of representatives of the competent regulatory authority to the so called "Transparency Tables" organized on a periodic base by the Regions where the nuclear facilities are located. Further, ISPRA prepares specific reports for Parliamentary Commissions.

With regard to ISPRA's website, ISPRA's Nuclear Department makes use of a dedicated section of ISPRA's website to provide information on its regulatory activities. Information on relevant licensing and supervision activities, as well as reports on international Conventions are posted on the Institute's Website. It is in particular done for technical guides, as it has been recently the case with the technical guide on siting criteria of a near surface disposal facility for low and intermediate radioactive waste.

In addition, in some occasions, press releases are also issued by the press office of the Institute. Further, according to the Italian legislation for both nuclear installations and for spent fuel and waste management facilities, the licensee has also to inform the workers and the population on the status of the nuclear safety of the installations. It is also obliged by the authorization to prepare an information plan to implement with periodic public hearings.

The IRRS team observed that on ISPRA's Website there is limited information on the website on the safety of the nuclear facilities. Further, in the IRRS team's view there are not enough activities that are specifically focused on the information of the public in the vicinity of the nuclear installations. The IRRS team was informed that all the previous information is punctual. ISPRA has identified that a more systematic approach has to be developed in the use of the Institute's website for the communication to interested parties and to the public.

ISPRA, interacts with interested parties as required by the Italian national legislative framework, but the IRRS team was told and understood from several discussions that ISPRA's communication and consultation activities are rather limited in scope and tend to focus on the official bodies, rather than the public. Further, the IRRS team observed that the national legislation does not envisage a system of consulting with the local population before an authorization relating to ionizing radiation is granted. The IRRS team noted that ISPRA is under a legal duty to provide information to the public. There is also a legal duty for licensees to provide the public with information. The Italian national legislative framework requires the provision of information to the public in respect of radiological emergency situations and provides for *"wide-ranging and detailed public information and communication campaigns"* in respect of the siting and development of the National Waste Repository.

Given that the conduct of dialogue with the interested parties will be absolutely critical for the success of the plan for development of the National Waste Repository, and important to successful regulation more generally, it is recommended that the regulatory body should provide information to, and consult with, parties affected by its decisions including the public. The IRRS team therefore concludes that a formalized process for consulting the public in its regulatory decision making should be developed.

This observation was also highlighted by the counterpart in the preliminary Action Plan for Italy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team was informed that ISPRA notifies interested parties on the principles and associated criteria for safety established in its guides, and makes them available. However, this is not executed in a consistent and systematic manner, but rather on a case-by-case basis. The IRRS team was informed that the communication with the interested parties is related to involved institutions and local communities in relation to regulatory processes. Furthermore, sufficient information about the radiation risks associated with facilities and activities is not made available, and it is only provided on a case by case basis.	
(1)	**BASIS: GSR Part 1(Rev.1) Requirement 34 states that** *"The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 34 para 4.61 states that** *"The*

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	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. Moreover, technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides."
(3)	**BASIS: GSR Part 1 (Rev.1) Requirement 36, para 4.66(c) states that** *"Communication of such documents and opinions from private or public organizations or persons to the regulatory body as may be considered necessary and appropriate;"*
(4)	**BASIS: GSR Part 3 Requirement 3, para 4.66 states that** *"The regulatory body shall establish a regulatory system for protection and safety that includes: ... (6) Provision of information to, and consultation with, parties affected by its decisions and, as appropriate, the public and other interested parties."*
(5)	**BASIS: GSR Part 1 (Rev.1) Requirement 36 para 4.67 states that** *"The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. 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. The results of these consultations shall be taken into consideration by the regulatory body in a transparent manner."*
(6)	**BASIS: GSR Part 2 Requirement 5 para 4.6 states that** *"Senior management shall identify interested parties for their organization and shall define an appropriate strategy for interaction with them."*
(7)	**BASIS: GSR Part 2 Requirement 5 para 4.7 states that** "*Senior management shall ensure that the processes and plans resulting from the strategy for interaction with the interested parties include:* (a) *Appropriate means of communicating routinely and effectively with and informing interested parties with regard to radiation risks associated with the operation of facilities and the conduct of activities;* *(b) Appropriate means of timely and effective communication with interested parties in circumstances that have changed or that were unanticipated;* *(c) Appropriate means of dissemination to interested parties of necessary information relevant to safety;* *(d) Appropriate means of considering in decision making processes the concerns*

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	and expectations of interested parties in relation to safety."
(8)	**BASIS: GSR Part 6 Requirement 11, para 7.16 states that** *"Interested parties shall be provided with opportunity to examine the final decommissioning plan and, as appropriate and subject to national regulations, supporting documents, and to provide comments prior to its approval."*
(9)	**BASIS: GSR Part 6 Requirement 5, para 3.33 states that** *"The responsibilities of the regulatory body shall include: … (6) - Providing interested parties with an opportunity to comment on the final decommissioning plan and supporting documents before their approval, on the basis of national regulations."*
R10	**Recommendation: The Government should enact specific provisions to foster consultation of interested parties in relevant licensing processes. The regulatory body should define a strategy and improve its processes and plans for communication and consultation with the public and other interested parties, on radiation risks associated with facilities and activities, and on the implementation of its regulatory functions.**

3.9. SUMMARY

ISPRA, the main regulatory authority in Italy, performs its functions in a manner that does not compromise its independence and meets the relevant IAEA safety requirements.

Regarding human resources, ISPRA should put in place a process on the long-term development of competence and skills of its staff, including training and retraining, in order to ensure the discharge of its regulatory duties and to compensate for the departure of qualified staff.

Due to insufficient financial resources, ISPRA is not able to adequately use support organizations to obtain technical or other expert professional advice or services, in support of its regulatory functions.

Clear mechanisms of communication are established between ISPRA and authorized parties. However, ISPRA should improve its processes and plans for the communication with interested parties and the public. Sufficient information about the radiation risks associated with facilities and activities should also be made available.

National registers of radiation sources and of doses from occupational exposure have not been established since the relevant decrees have not been enacted.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

The Competent Regulatory Authority prepared for the module 4 a very comprehensive ARM report where the activities of the Regulatory Body are compared against the IAEA Safety Standard GS-R-3 Management System for Facilities and Activities. Since meanwhile the new IAEA Safety Standard was issued, namely, GSR Part 2, "Leadership and Management for Safety" which supersedes the GS-R-3, the IRRS report takes into consideration the requirements of the new IAEA Safety Standard GSR Part 2.

In this section, the term "regulatory body" refers to the Nuclear, Technological and Industrial Risk Department of ISPRA.

4.1. LEADERSHIP FOR SAFETY

According to the IAEA Safety Standard GSR Part 2, leadership for safety can, among other, be expressed also through establishing vision, mission, values, establishing behavioral expectations and fostering a strong safety culture.

The regulatory body has defined its mission which is to assure the radiation protection of the workers, people and environment and the nuclear safety of activities. The mission is published in the document "Institutional Functions of Nuclear, Technological and Industrial Risk Department" issued in 2007 and available on the ISPRA website.

The priority to safety and to safety culture could be recognized through the description of the functional responsibilities defined in the document "Institutional Functions of Nuclear, Technological and Industrial Risk Department" issued in 2007".

In the ARM it is considered that different existing elements of the management system have to be further developed and collected in an integrated manner. In this regard a Management Manual is under preparation.

The IRRS team was informed that in the development of its own Management System, the regulatory body will formalize the systematic approach in demonstration of leadership for safety, including i.e.:

- Vision, behavioural expectations, individual and institutional values and expectation for safety;
- Processes for regularly familiarizing employees with the regulatory body's organizational policy, safety policy, mission, vision, values;
- Processes for regularly familiarizing all employees with information important for the regulatory body and its activity.

4.2. MANAGEMENT FOR SAFETY

RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

It is the responsibility of the senior management to ensure that an integrated management system is established, implemented, assessed and continually improved. This responsibility is now defined in the document "Institutional Functions of Nuclear, Technological and Industrial Risk Department" issued in 2007. Division and Section Heads of the regulatory body are committed to the development of a management system. The IRRS team noted that more

resources would be needed in order to establish, apply, sustain and continuously improve the integrated management system. This issue is addressed in Section 1.3 Recommendation R3.

In 2014, ISPRA developed a document named "Declaration of Quality Policy". As ISPRA Declaration of Quality Policy does not include the elements of safety policy, the regulatory body intends to develop its own policy in the framework of the regulatory body's management system.

The IRRS team has been informed that the management manual under preparation will include the policy declaration of the organization to achieve and enhance safety.

The IRRS team observed that an integrated management policy, including among others organizational policy, safety policy and enforcement policy is not in place. This issue is addressed in Recommendation R11 in Module 4 and Suggestion S13 in Module 8.

The senior management ensures measurable goals, strategies, plans and objectives through the ISPRA performance plan. A performance assessment system is implemented by ISPRA organization on the bases of Law Decree No. 150/2009 (mandatory for all Public Administrations) which establishes requirements and procedures for public administrations to enhance their qualitative and economic performance standards and professional competences of the personnel.

The IRRS team was informed that, for the regulatory body, strategic objectives, operational objectives, products and key performance indicators are defined for 5 strategic areas (Networking, Monitoring, Technical Support and Counseling, Regulations, Reporting). Operational objectives are defined every three years and a system for the measurement and evaluation of the organizational performance is implemented. The system is based on the definition and assignment of performance objectives and measurable key performance indicators. The associated monitoring of results is performed every year with an intermediate verification in the first semester to allow adjustments and address deviations from the original plan.

The regulatory body is well aware of the interested parties, i.e. licensees, Ministries, public associations, etc. The IRRS team was informed that interested parties for specific areas are defined in different documents. Senior management collects and takes into account the expectations of the interested parties with the aim to provide adequate solutions, while ensuring that safety is given priority in all regulatory activities. An important mean to provide information is represented by the participation of representatives of the regulatory body to the so called "Transparency Tables" organized on a periodic base by the Regions where the concerned nuclear installations are located. Most of the reports on the Transparency Tables are published on the ISPRA website. The Action Plan also identifies the need for a more systematic approach to the use of the institutional website for communication to the interested parties and public is needed.

IRRS team noted that interested parties of the regulatory body are not systematically identified in the management system; however the IRRS team was informed that they will be in the future. The interaction with different interested parties as well as coordination between different Ministries and authorities that are involved in the regulatory control are not systematically documented. This issue is addressed in Module 1 Suggestion S1. Further, the strategy for interacting with the interested parties and the processes resulting from this strategy are not identified. This issue is addressed in Module 3 Recommendation R10.

THE MANAGEMENT SYSTEM

As stated in the ARM documents, the management system of the regulatory body is based on the organizational structure defined in the document Institutional Functions of Nuclear, Technological and Industrial Risk Department issued in 2007 within the Decree of the Commissioner of APAT. ISPRA has developed a quality management system in line with ISO 9001:2008 standard. The regulatory body is a part of this quality management system; some sections of the regulatory body have an ISO certificate (i.e. Radiometric Measures Division).

The regulatory body has not systematically developed an integrated management system that brings together in a coherent manner all the requirements for managing the organization. This issue is addressed in Recommendation R11 below. The regulatory body considers that the different existing elements of the management system have to be systematically developed and collected in an integrated manner. Currently, the development of the regulatory body's own management system is in the initial phase and under development.

Only some parts of the regulatory body management system are documented and are in line with the requirements of IAEA safety standards. The management system manual is under the preparation. The Action Plan identified that the development of an integrated management system has to be completed, including the issuing of a comprehensive management manual of procedures related to all relevant processes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulatory body has not yet established and implemented an integrated management system in line with international standards. The IRRS team observed that activities are in progress for the development of the various elements of the system.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."*
(2)	**BASIS: GSR Part 2 Requirement 6 states that** *"The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised."*
(3)	**BASIS: GS-G 3.1 para 2.1. states that** *"An integrated management system should provide a single framework for the arrangements and processes necessary to address all the goals of the organization. These goals include safety, health, environmental, security, quality and economic elements and other considerations such as social responsibility."*
(4)	**BASIS: GSR Part 2 Requirement 13 states that** *"The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety."*
R11	**Recommendation: The regulatory body should establish, implement and continuously improve an integrated management system in line with IAEA safety standards.**

The IRRS team noted that:

- The plan for establishing and implementing the management system does not exist. This issue is addressed in Suggestion S3 below.
- A Quality Management Officer and a team responsible for developing and implementing the integrated management system are not formally assigned;
- Training related to the establishment, introduction, implementation and continuously improvement of the management system for the responsible team and for all employees has not been provided.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulatory body has not foreseen the preparation of an implementation plan in order to develop an integrated management system in an efficient manner.	
(1)	**BASIS: GS-G-3.1 para 2.24 states that** *"Senior management should prepare a plan to achieve full implementation of the management system."*
S3	**Suggestion: The regulatory body should consider developing a plan for the establishment and implementation of the integrated management system where, among others, key priorities are pointed out, and interactions between the processes are defined.**

The ARM report states that the application of the graded approach to the management system in practice is used in the implementation of different regulatory activities. The deployment of resources is optimized by the establishment of working groups on complex activities taking into account a graded approach with regard to the relevance of the conducted regulatory activities in relation to the hazard of the different installations. However, it was noted that graded approach is not documented, as well as, criteria used to grade the development and application of the management system are not defined in the framework of the management system. This issue is addressed in Recommendation R11 above.

IRRS team noted that management system documentation is limited as follows:

- Description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work, found in "Institutional Functions of Nuclear, Technological and Industrial Risk Department", 2007;
- Organizational chart;
- Management system manual in preparatory phase and several drafts of procedures attached to this manual.

Following documents are not included into the regulatory body's management system documentation:

- Policy statements of the organization on values and organizational expectations;
- The fundamental safety objectives;
- A description how the management system complies with the regulatory requirements that apply to the organization;

- A description of the processes;
- A description of the interactions with external organizations and with interested parties. This issue is addressed in Recommendation R10 in Module 3.

MANAGEMENT OF RESOURCES

As already mentioned, senior management determines how to employ the available resources to carry out the regulatory activities on the basis of the ISPRA Performance Plan.

The competence requirements for individuals are determined by the evaluation of educational qualification, curriculum vitae, and previous experiences. As described in the ARM report, attention is given to the development of staff competence as well as to the transfer of knowledge. The competence of the personnel is verified during the implementation of the various regulatory activities and within the internal review process.

The knowledge management is currently performed through the recording of all technical documents in an electronic archive named ARIS. Access to the archive is for all the technical staff of the regulatory body so as to ensure an easy retrieval of documentation and information (e.g. authorization data of a facility, internal technical reports, inspection reports, relative correspondence, legislative and literature references). The regulatory body has developed a document "Knowledge Management Program", which is not in use. The document defines the educational, training and competences requirements for the regulatory body in order to plan the needs for different resources. The document is based on the IAEA TECDOC Series No. 1254.

The IRRS team observed that the systematic approach to the knowledge management is not in place as well as a systematic approach to training on the basis of competences skills and working tasks is not established. This issue is addressed in Recommendation R7 in Module 3. It was as well observed that training plans are not in place.

In the last years, it has not been possible for regulatory body to recruit new personnel. In this view the staffing plans have not been prepared. This issue is also addressed in Recommendation R7 in Module 3.

MANAGEMENT OF PROCESSES AND ACTIVITIES

The different processes of the regulatory body are identified according to a consolidated practice. The core processes implemented by the regulatory body are identified in the Legislative Decree No. 230 /1995 and in the Legislative Decree No. 45/2014.

IRRS team observed that the regulatory body's processes are not formalized and documented in line with IAEA Safety Standards related to the integrated management systems. This issue is addressed in Recommendation R11 above.

- The process map identifying management, core and supporting processes is not defined;
- Management, core and supporting processes are not developed;
- Process owners are not assigned;
- Sequencing of the process is not defined;
- The interactions between processes within the regulatory body and the interactions between processes conducted by the regulatory body and processes conducted by external parties are not specified.

4.3. CULTURE FOR SAFETY

Some elements of safety culture are applied in several activities implemented by the regulatory body. However, the culture for safety of the regulatory body is not directly addressed in regulatory body's organizational documents. This issue is addressed in Recommendation R12 below. IRRS team observed that the management system should be developed so as to foster and sustain a strong culture for safety.

The IRRS team has been informed that, in relation to safety culture, even if is not directly addressed in the ISPRA organizational documents, the related principle is applied in several activities carried out taking into account the international safety standard and national nuclear safety and radiation protection legislation.

Furthermore, the operational objectives of the actual ISPRA Performance Plan are related to safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The culture for safety is not explicitly addressed in the regulatory body's organizational documents.	
(1)	**BASIS: GSR Part 2 Requirement 12 states that** *"Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture*."
(2)	**BASIS: GSR Part 2 Requirement 12 para 5.2 states that** *"Senior managers and all other managers shall advocate and support the following:* *(a) A common understanding of safety and of safety culture, including:* *awareness of radiation risks and hazards relating to work and to the working environment; an understanding of the significance of radiation risks and hazards for safety; and a collective commitment to safety by teams and individuals;* *(b) Acceptance by individuals of personal accountability for their attitudes and conduct with regard to safety;* *(c) An organizational culture that supports and encourages trust, collaboration, consultation and communication;* *(d) The reporting of problems relating to technical, human and organizational factors and reporting of any deficiencies in structures, systems and components to avoid degradation of safety, including the timely acknowledgement of, and reporting back of, actions taken;* *(e) Measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;* *(f) The means by which the organization seeks to enhance safety and to foster and sustain a strong safety culture, and using a systemic approach* *(i.e. an approach relating to the system as a whole in which the interactions between technical, human and organizational factors are duly considered);* *(g) Safety oriented decision making in all activities;* *(h) The exchange of ideas between, and the combination of, safety culture and security culture."*
(3)	**BASIS: GS-G-3.1 para 3.2 states that** *"the management system should provide*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	structure and direction to the organization in a way that permits and promotes the development of a strong safety culture."
R12	**Recommendation: The management system of the regulatory body should be developed so as to foster, in a documented manner, a strong safety culture and provide structure and direction in a way that permits and promotes the development of such a culture.**

4.4. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Measurement, assessment and improvement processes are mainly related to the evaluation of performed activities developed in the ISPRA Performance Plan. The ARM report highlights that the reviews of key activities are performed on regularly basis through the implementation of the ISPRA Performance Plan. The scope of the reviews, performed every six months, is to verify the fulfilment of the established performance objectives. The outputs coming from this review are used as input to improve the processes and the results are used as a tool to identify the weakness of the organization and to improve the performances of the regulatory body. The ISPRA Performance Plan can be used for performing a self-assessment to evaluate the performance of the work carried out.

The IRRS team observed that following measurement, assessment and improvement processes are not documented and not regularly and systematically implemented. This issue is addressed in Recommendation R11 above:

- Conducting internal assessments (internal audits);
- Conducting self-assessments of management system;
- Conducting self-assessments of safety culture;
- Conducting management system reviews.

4.5. SUMMARY

The Management system of the regulatory body is based on the organizational structure defined in the document "Institutional Functions of Nuclear, Technological and Industrial Risk Department", issued in 2007. The current management system of the regulatory body is a part of ISPRA quality management system which is based on ISO 9001:2008 standard.

The management system of the regulatory body has not been established and implemented in line with the requirements of IAEA Safety Standard GSR Part 2, Leadership and Management for Safety.

In the Action Plan the regulatory body has recognized the need for the establishment and implementation of its own management system, which supports the enhancement and improvement of a strong culture and achievements of safety goals.

5. AUTHORIZATION

5.1. GENERIC ISSUES

Authorizations related to nuclear facilities, major activities with the use of ionizing radiation and the use of sources of category A are issued by the Ministry of Economic Development. They are granted on the base of a binding technical advice provided by ISPRA, which includes technical specifications, and taking into account observations of other relevant ministries (Ministries of Environment, Interior, Labour and Health) and the Region concerned. For radiation sources of category B, the license for medical uses is issued by authorities identified by the Regions and, for all other cases, by the Prefect, based on the advice of a local technical committee. The licensing process is presented in more detail in Module 1.

The IRRS team was informed that for the different stages of the life (e.g. siting, construction, operation, decommissioning) of the nuclear installations the above mentioned authorization by the Ministry of Economic Development is issued based upon comprehensive safety cases (e.g. PSAR in case of construction, global decommissioning plan for decommissioning). The licensing system establishes that in the authorizations all safety related systems and activities and/or operations (in the case of decommissioning) are identified. After the authorization is granted, before being implemented the detailed designs of safety related systems or operations have to be approved by the competent regulatory authority, based upon the submittal of detailed projects or plans of operation in which consistency with general safety criteria and requirements assumed as reference in the authorization has to be demonstrated. After the approval the competent regulatory authority conducts its supervision activity on the construction and implementation.

The IRRS team had discussions with various national and regional authorities to clarify their roles and responsibilities in the Italian licensing system, as they are presented in more detail in Module 1.

The public participation in the licensing processes is limited. This issue is addressed in Recommendation R10 in Module 3. The IRRS team observed that towards the applicants and licensee, the licensing procedure is rather transparent.

The personnel to conduct operations of nuclear facilities is certified. The certification is issued by the competent local office of the Ministry of Labor after the verification of the technical skills and health conditions by dedicated commission coordinated by ISPRA. This certification is renewed periodically every 3 years. The renewal is based on specific requirements for health and with regard to a minimal effective time on duty of the personnel. Although there are requirements for up-dating technical skills, it is not verified as part of the renewal process if the knowledge of the operator is still appropriate. This issue is addressed in Suggestion S4 in this module.

Other aspects related to authorization are more specific and treated therefore in the following sub-sections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team observed that although, in order to grant to operators of nuclear facilities qualification certificates, it is required to examine their technical skill, time of experience and health fitness. At the renewal every three years, it is however not verified if technical skills are still fit for purpose.	
(1)	**BASIS: NS-G-4.5, para 5.12 states that** *"The competence of authorized persons should be reviewed periodically. Consideration should be given to the need for periodic reauthorization. In many States, authorizations issued by the regulatory body are generally valid for a limited time, typically from one to six years. An authorization may be withdrawn or not renewed if the individual no longer meets the requirements for performing the duties of the authorized position or is no longer needed to perform the authorized duties. The decision to reauthorize an individual should be based, in part, on the person's passing a medical examination. Each authorized individual should successfully complete the continuing training programme appropriate to his or her position and should pass the requalification examination."*
(2)	**BASIS: NS-G-2.8 para 7.12 states that** *"Consideration should be given to the need for periodic re-authorization. The authorization is generally subject to periodic reviews (at intervals of 2–3 years) of the competence of the authorized person."*
S4	**Suggestion: The regulatory body should consider the verification of technical skills in the process of renewing operators Certificates of Qualification for nuclear facilities.**

5.2. AUTHORIZATION OF RESEARCH REACTORS

The regulatory framework for authorization of research reactors (RR) is the same as for nuclear power plants. Technical conditions are attached to the authorization for operation (Operating Licence) and therewith made binding. For RR with a thermal output less than 100 kW the procedure is simplified.

The adequacy of the design of research reactors and its Structures, Systems and Components (SSC) are verified in the approval process as required by Art. 41 of the Legislative Decree No. 230/95.

However, the IRRS team noted that specifc safety requirements for the long-term shutdown state of RRs are not currently established. This issue is addressed in Suggestion S5 below. The extended shuthdown state is treated as normal operation. It could be extended up to decommissioning, without requiring a new or modified license.

The final safety analysis report (in the following text FSAR) is a basic document for RR modification approval. All modifications of FSAR are notified to ISPRA and are subject of full authorization process. In that case, the procedure applied is the same as for the operating licence but limited to the modifications. The Technical Guide No. 2 describes the process for modification. However, there are no formalized requirements and criteria for the safety classification of any other modification. The classification is based on the engineering judgment of ISPRA, according to a case-by case decision.

The IRRS team was informed that it is already in place a process in order to implement the PSR review in a more systematic way in the existing five-year report.

Art. 6 of Act No. 1860/1962 require that any modification, as defined in TG 2, in the RR must be authorized. For a modification is intended any change in the characteristics of the nuclear facility compared to those resulting from Final Safety Analysis Report. The FSAR has therefore to be updated to reflect the actual state of the installation. This issue is addressed in Suggestion S6 in this Module.

The authorization is granted by the Ministry of Economic Development based upon the binding technical advice of ISPRA.

Decommissioning for RRs is a standalone authorization.

The IRRS team has observed that the competence of the personnel of RRs is not assessed when their certificates are renewed. This issue is addressed in Section 5.1. Suggestion S4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team observed that there are no safety requirements in place for the long-term shutdown state of research reactors. It is possible that a research reactor may be in long-term shutdown just before decommissioning or for economic, political or other reason.	
(1)	**BASIS: SSG-12, req. 3.80 states that** *"The licensee should submit to the regulatory body for authorization the specifications for maintaining the safety and security of the nuclear installation during long term shutdown. The regulatory body should review, assess and inspect such specifications and may attach conditions."*
(2)	**BASIS SSR-3 that Requirement 38 states *that*** *"Provision for long shutdown periods:* *In the design of the research reactor facility, consideration shall be given to ensuring the safety of the facility in long shutdown periods."*
S5	**Suggestion: The regulatory body should consider establishing safety requirements for a research reactor in long term shutdown.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The IRRS team observed that the Safety Analysis Reports are not updated as a result of the periodic safety review of the research reactors.
(1)	**BASIS. SSR-3, Requirement 1 states that** "*Safety analysis report: A safety analysis report shall be prepared by the operating organization for a research reactor facility. The safety analysis report shall provide a justification of the site and the design and shall provide a basis for the safe operation of the research reactor. The safety analysis report shall be reviewed and assessed by the regulatory body before the research reactor project is authorized to progress to the next stage. The safety analysis report shall be periodically updated over the research reactor's operating lifetime to reflect modifications made to the facility*

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	and on the basis of experience and in accordance with regulatory requirements."
(2)	**BASIS: GSR Part 4, Requirement 20 para 4.65 states that** "*The safety report is to be updated as necessary. The safety report has to be retained until the facility has been fully decommissioned and dismantled or the activity has been terminated and released from regulatory control. For a repository for radioactive waste, the safety report has to be retained for an extended period of time after closure of the repository".*
S6	**Suggestion: The regulatory body should consider ensuring that the Safety Analysis Report has to be revised also as a result of the periodic safety reviews so that it reflects its actual status.**

5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

For the licensing of predisposal radioactive waste management facilities the applicant shall submit a safety analysis report containing all the demonstrations and evaluations of the respect of the safety requirements established by the legislative framework. The standard content of documents to be submitted is detailed in Chapter VII of Legislative Decree No. 230/1995. Nevertheless the required information is not enough to comply with IAEA safety requirements on safety assessment and safety case. The IRRS Team was however informed that the IAEA safety standard as well as the WENRA safety reference levels are taken into account in the licensing process. Currently a "Technical Guidance" on safe storage of radioactive waste is being developed that should complement requirements in force in this regard. This issue is addressed in Recommendation R26 in Module 9.

Legislative Decree No. 31 of 15 February 2010 describes procedures for the siting, construction and operation of the National Repository for the disposal of low and intermediate radioactive waste and the long term storage of long lived ILW and HLW and of the technology park. This Decree specifies the time periods for components of the disposal siting and licensing process, including for public consultation/participation and for the review of the Licence Application by the regulatory body. Decree No. 31/2010 also specifies that a single licence would be granted covering both the construction and operation of both the disposal facility and the long term storage facility. Internationally, experience in the siting and licensing of national radioactive waste disposal facilities has shown that it is important to have flexibility in the timeframes. This is because of the scale and complexity of a licence application and safety case for a disposal facility, the independent review and assessment of the proposals for the disposal facility by the regulatory body usually lasting on the order of at least one to several years.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Legislative Decree No. 31/2010 specifies fixed time periods for the steps of the repository siting and licensing processes, including periods for public involvement and for the review of the licence application. In some cases the pre-defined time periods appear to be too short. Furthermore, the Legislative Decree No. 31/2010 specifies that a single licence is provided for both the construction and operation of the disposal facility.	
(1)	**BASIS: SSR-5 Requirement 11 states that** *"Disposal facilities for radioactive waste shall be developed, operated and closed in a series of steps. Each of these*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	steps shall be supported, as necessary, by iterative evaluations of the site, of the options for design, construction, operation and management, and of the performance and safety of the disposal system."
(2)	**BASIS: SSR-5 Requirement 11 para 4.4 states that** "*The step by step approach to the development of a disposal facility also allows opportunities for independent technical review, regulatory review, and political and public involvement in the process."*
(3)	**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."*
(4)	**BASIS: GSR Part 1 (Rev.1) Requirement 24 para 4.29, states that** *"Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity."*
(5)	**BASIS: GSR Part 1 (Rev.1) Requirement 24 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."*
R13	**Recommendation: The Government should ensure that disposal facilities for radioactive waste are developed, operated and closed in a series of steps (site selection and evaluation, facility design, construction, operation, closure, institutional control). Each of these steps should be supported, as necessary, by iterative evaluations of the safety of the disposal system. In particular the legislative provisions should envisage separate authorizations for different stages in the lifetime of the facility and adequate time periods for regulatory review and assessment.**

5.4. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The regulatory body has records of approximately 90 licensees holding category A radiation sources and 1500 licensees holding category B radiation sources for industrial proposes, but nearly no information on licensees of category B radiation sources involving exposure for medical purposes, despite the legal provision that a copy of the license shall be submitted to ISPRA. In the latter case, LG-230/1995 provides that by the laws of the regions and autonomous provinces, the competent local authorities and procedures for licensing these sources shall be determined. The IRRS team was able to review an example of such a law concerning the Piedmont region, but neither ISPRA, nor the Ministry of Health has a list of all local authorities in charge with the regulatory control of radiation sources. The need for better coordination of the regulatory functions between national and regional authorities is reflected in general terms in Module 1 Suggestion S1.

The license applicant has for both categories, A and B to produce the same documents. Also the legislation does not provide for the safety assessment to be commensurate with the radiation risks associated. This issue is addressed in Suggestion S7.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: According to the Legislative Decree 230/1995, the list of the documents required in support of an authorization application are the same for category A and category B radiation sources.	
(1)	**GSR Part 1 (Rev.1) Requirement 24, para 4.33 states that** *"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."*
S7	**Suggestion: The regulatory body should consider applying a graded approach within the authorization of radiation sources.**

During a visit to the Gemelli hospital, the team was told that they have frequent professional exchanges with ISPRA during a licensing procedure. Also, the licensee receives a draft of the license 30 days before it is officially issued.

For category A radiation sources, such as for a cyclotron, the authorization is issued in a single stage, comprising the permit to install the facility and to operate it. Even though there may be a single license, the process should include a mechanism for ISPRA to review the safety of the facility before it starts operation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The legal framework requires that for radiation sources, such as for a cyclotron, a single authorization is issued by the Ministry of Economic Development, which includes the permit to install the facility and to operate it.	
(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 1 (Rev.1) Requirement 24, para 4.29 states that** *"Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas. For radioactive sources and radiation generators, the regulatory process shall continue over their entire lifetime."*
(3)	**BASIS: GSR Part 1 (Rev.1) Requirement 24, para 4.30 states that** "*Authorization for a facility shall include authorization of the activities taking place at the facility (e.g. operation, maintenance and engineering activities)."*
(4)	**BASIS: GSR Part 1 (Rev.1) Requirement 24, para 4.35 states that** *"Some of the stages in the lifetime of a facility or the duration of an activity (see para. 4.29) may require specific hold points at which separate authorizations are required."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R14	**Recommendation: The Government should review the legal framework for authorization of radiation sources in order to introduce, in relation to the risk of the installation, a mechanism which includes a series of steps (e.g. facility design, construction, operation, closure) to be consistent with IAEA Safety Standards and taking into account the graded approach.**

With regard to category B sources for medical use, the authorization process is different from a region to another. In fact, the competent authorities, technical advisory bodies and other aspects of the regulatory control are defined in regional laws, and therefor different across Italy. In case of category B sources used in industrial applications, the Prefectures grant licenses, as defines in Legislative Decree No. 230/1995. However, in those cases the consistency of the review of the safety assessment and the definition of licensing conditions is not unified. No practical instructions or guidance exist for regional authorities and Prefectures to enable them the deliberation of their regulatory function in a consistent way. This issue is addressed by Recommendation R15 below.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: For category B sources, a common procedure or mechanism to ensure consistency between the local authorities in the authorization process is not in place.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 4 para 2.12, states that** "*Where several authorities are involved in the authorization process, the regulatory requirements shall apply, and they shall be applied consistently and without undue modification.*"
R15	**Recommendation: The Government should ensure the consistency in the authorization process of category B sources.**

A strong point in the authorization process for radiation sources is the inclusion of a highly qualified expert. However this expert, whether he is part of the licensee staff or external, both writes the safety assessment and reviews it before submitting the license application. Though it is recognized that the issue of an independent review of the license application should be imposed following a graded approach, the complete lacking of such arrangements in the area of radiation sources is addressed in Suggestion S8 below.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The existing legislation requires that a safety assessment be performed by a qualified expert in support of the application for an authorization. In practice, the qualified expert both writes and reviews the safety assessment before the submittal of the license application. Consequently there is no independent verification of the safety assessment.	
(1)	**BASIS: GSR Part 4 Requirement 21, para 4.66 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."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 4 Requirement 21, para 4.67 states that** *"The independent verification is performed by suitably qualified and experienced individuals or a group different from those who carried out the safety assessment. The aim of independent verification is to determine whether the safety assessment has been carried out in an acceptable way."*
S8	**Suggestion: The regulatory body should consider requiring an independent verification of the safety assessment, as appropriate taking into account a graded approach, for radiation sources before it is submitted to the regulatory body.**

5.5. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Legislative Decree No. 230/1995 requires in Article 55 that the decommissioning of a nuclear installation is subject to prior authorization from the Ministry of Economic Development. It is stated that this authorization may be granted, if necessary, for single intermediate phases.

The documentation to be presented as support to an application for a licence is described only in Legislative Decree No. 230/1995, Article 55 and subsequent item 1) to 3). These requirements do not detail all the information internationally recommended in IAEA Safety Standards (GSR Part 6 and WS-G-2.1 Decommissioning of Nuclear Power Plants and Research Reactors). The article 56 4) requires that the authorization for decommissioning is issued by the Ministry of Economic Development conditioning it to compliance with any relevant conditions and specifications established by ISPRA. ISPRA indicated to the IRRS team that the conditions and specifications established by the Ministry of Economic Development are an endorsement of the requirements developed by ISPRA. Regarding decommissioning, ISPRA indicated that a technical guide is under development which will provide the list of documents to be submitted by the applicant in support to an authorization for decommissioning. The IRRS team has been informed that specific legislative provisions are not in place to require that a decommissioning plan has to be in place and periodically updated during the operation of research reactors and waste facilities.

GSR Part 6 requires that for existing installations a decommissioning plan should be developed by the licensee as soon as possible.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The legal and regulatory framework does not require that decommissioning plans are developed and submitted to the regulatory body for review and assessment during the lifetime of a nuclear facility. The IRRS team was informed that no provisions are in place for the decommissioning of research reactors and for storage facilities.	
(1)	**BASIS: GSR Part 6 Requirement 10, para 7.7 states that** *"If permanent shutdown takes place before a final decommissioning plan has been prepared, such a plan shall be prepared as soon as possible and adequate arrangements shall be made to ensure the safety of the facility until the approval of the final decommissioning plan."*
(2)	**BASIS: GSR Part 6 Requirement 11 states that** *"Prior to the conduct of*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	decommissioning actions a final decommissioning plan shall be prepared and shall be submitted to the regulatory body for approval."
(3)	**BASIS: GSR Part 1 (Rev.1) Requirement 24, 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."*
(4)	**BASIS: GSR Part 6 Requirement 11, para 7.9 states that** *"If a facility is permanently shut down and/or is no longer used for its intended purpose, a final decommissioning plan shall be submitted to the regulatory body for approval within a period agreed with the regulatory body (typically within two to five years of permanent shutdown).*
(5)	**BASIS: GSR Part 6 Requirement 11, para 7.10 states that** *"The final decommissioning plan and supporting documents shall cover the following: the selected decommissioning strategy; the schedule, type and sequence of decommissioning actions; the waste management strategy applied, including clearance, the proposed end state and how the licensee will demonstrate that the end state has been achieved; the storage and disposal of the waste from decommissioning, the timeframe for decommissioning, and financing for the completion of decommissioning."*
(6)	**BASIS: GSR Part 6 Requirement 3, para 2.6 states that** *"The final decommissioning plan shall be supported by a safety assessment addressing the planned decommissioning actions and incidents, including accidents that may occur or situations that may arise during decommissioning."*
(7)	**BASIS: GSR Part 6 Requirement 11, para 7.16 states that** *"Interested parties shall be provided with opportunity to examine the final decommissioning plan and, as appropriate and subject to national regulations, supporting documents, and to provide comments prior to its approval."*
R16	**Recommendation: The Government should establish provisions for the preparation of decommissioning plans, in accordance with IAEA safety standards, for new and for existing facilities that have not submitted a decommissioning plan.**

The IRRS team examined the content of the Decree of the Ministry of Economic Development 28 September 2012 "Decommissioning in a single phase, until the release of the site without radiological constraints, of the Garigliano Nuclear Power Plant". It has been observed that the objectives of this license is to allow to carry out the activities related to the accelerated decommissioning in a single phase until the unconditional release of the site.

Nevertheless, it is stated in the Decree that the decommissioning of the nuclear island starts only if there is the availability of suitable facilities for the temporary storage of radioactive waste on site, in the wait of their transfer to the National Repository. In addition, it is required in the annex 2 of the decree that the decommissioning activities shall be developed through

Decommissioning Projects which are subject to prior approval by ISPRA. These activities are identified in this annex and are:

- Interim storage of radioactive waste;
- Realization and refurbishment of plant systems;
- Decommissioning inside the reactor buildings;
- Decommissioning inside the auxiliary buildings
- Final remediation, monitoring and clearance of the site.

Furthermore, it is indicated in the annex 2 that the projects numbering does not mean a time issuing sequence and that projects may be submitted for approval also in separate parts (Detailed Projects and/or Plans of Operations). For interim storage facility, it is indicated by annex 2 that the project also covers the possible construction of new temporary storage facilities. The sequence, timeframe and endpoints of decommissioning activities are described in the Global Decommissioning Plan.

This licensing process implies that safety related activities as highlighted in the decommissioning decree have to be undertaken after a prior approval by ISPRA.

References to the safety standards used, including the IAEA standards, are specified in the review, assessment and subsequent approval of detailed projects by ISPRA. It is to be mentioned that ISPRA has actively participated in the development of WENRA Safety Reference Levels (SRL), in particular for those related to waste storage facilities and decommissioning. The WENRA SRLs have been explicitly referred to in the authorization documents and they have been transposed into new technical guides, which are in the final stage of preparation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Although some of the Italian legal and regulatory requirements and guidance for nuclear safety are not up to date, ISPRA incorporates into its individual approvals, the "state of the art" of safety standards developed by other regulatory bodies. The IAEA team observed that the approval issued by ISPRA in 2015 for the construction of a new treatment system for liquid radioactive waste at Garigliano NPP requires that the mechanical components for the collection, transfer and handling of radioactive liquids shall be made in accordance with technical standards specified in the US NRC RG 1.26.	
(1)	**BASIS: GSR Part 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."*
(2)	**BASIS: GSR Part 1 Requirement 14, para. 3.2 states that "***The features of the global safety regime include:* *a) International conventions that establish common obligations and mechanisms for ensuring protection and safety;* *b) Codes of conduct that promote the adoption of good practices in the relevant facilities and activities;* *c) Internationally agreed IAEA safety standards that promote the development and application of internationally harmonized safety requirements, guides and practices;* *d) International peer reviews of the regulatory control and safety of facilities and activities, and mutual learning by participating States;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	e) Regular multilateral and bilateral cooperation between the relevant national and international organizations to enhance safety by means of harmonized approaches as well as to increase the quality and effectiveness of safety reviews and inspections, by means of sharing of knowledge and feedback of experience."
GP1	**Good Practice: The use of up to date, state of the art safety standards from foreign regulatory bodies by ISPRA in the field of decommissioning and waste management, in order to cover gaps in the Italian framework, pending further regulatory updates, is considered to be a good practice because it requires a superior performance to what is commonly observed in decommissioning and in the on-site design, construction and operation of waste treatment facilities.**

5.6. AUTHORIZATION OF TRANSPORT

The transport of radioactive material is part of the transport of dangerous goods. The UN Model Regulations use a classification system in which each dangerous substance or article is assigned to a Class, depending on the nature of the danger that it presents. The radioactive material is assigned to Class 7. Approximately 200,000 packages containing radioactive material are transported in Italy each year that represent about 2% of the entire movement of dangerous goods.

The majority of the excepted packages, industrial packages and Type A packages, which are not subject to competent authority approval. Type B packages and packages for fissile material, which are subject to competent authority approval, are also in use. All of Type B packages transported are of foreign design.

The majority of the shipments are related to the use of radioactive material for medical purposes, industry (non-nuclear), for research and for transport of radioactive waste. The shipments in the nuclear fuel cycle are related essentially to the research reactors and to the decommissioning activities of the nuclear power plants. The spent fuel coming from the operations of NPPs was sent abroad during the last decade for reprocessing. A small number of spent fuel assemblies still stored in a facility will be sent for reprocessing in the next few years. A larger number of return shipments of high level vitrified waste to Italy will take place in the future, starting in about 2020.

The requirements of the IAEA Transport Regulations SSR-6 are fully implemented through the international model transport regulations for dangerous goods for Class 7 and must be applied by law in Italy for road, rail, inland waterway, sea and air transport (ADR, RID, ADN, IMDG-Code, ICAO-TI). Based on this, all approval requirements ("approval" is used in SSR-6 instead of "authorization") for the transport of radioactive material in Italy are in compliance with SSR-6, for which ISPRA issues the appropriate approval certificates. The IRRS team noted that some procedures and guides are currently under development for the various approval types as part of the management system (see Section 9.6).

In addition, there is a requirement for authorization of carriers based on the Nuclear Energy Act and the Radiation Protection Act, which must also be observed for the transport of radioactive material in Italy. There is a link to SSR-6 in so far, that the provisions of the IAEA Regulations SSR-6 are taken into account during the process for the authorization of the carrier. The

Ministry for Economic Development is designated as regulatory body (competent authority) to issue this authorization. ISPRA is involved as advisor as well as other ministries depending on the mode of transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The authorization of carriers is required according to the Act on Peaceful Use of Nuclear Energy and the Radiation Protection Act in Italy for which the Ministry for Economic Development is designated as regulatory body. For this authorization ISPRA is involved as advisor as well as other ministries depending on the mode of transport. However, there is no clear assignment of responsibilities and tasks for the various involved parties. The advice from ISPRA includes some aspects of SSR-6 (Radiation Protection Programme, training, material classification).	
(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 provisions for the effective coordination of their regulatory functions, to avoid any omissions or undue duplications and to avoid conflicting requirements being placed on authorized parties."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 23 states that** *"Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."*
(3)	**BASIS: GSR Part 1 (Rev. 1) Requirement 2 Para 2.6 states that** *"Where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within the governmental, legal and regulatory framework for safety."*
R17	**Recommendation: The Government should review and accordingly revise the authorization process for carriers regarding the:** - **legal responsibilities and needs of involved parties** - **specification of conditions for authorization** - **implementation of a graded approach** - **consistency with exemption requirements for authorization based on SSR-6** **to achieve a transparent, effective and simplified authorization process for all modes of transport.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: There are no new manufactured packagings in Italy which are subject to competent authority approval, but there are many older packaging in use for which appropriate maintenance operations and inspections are very important. Such maintenance and service activities must be performed within a certain time frame to guarantee that the package design during its use still meets all applicable requirements as part of the quality assurance program. It is not requested by ISPRA that such dates for performing maintenance and service activities are indicated on the packaging itself.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: TS-G-1.5 para 4.96 states that** "*It should be indicated on the packaging when the last maintenance or service operation was done or, preferably, when the next maintenance or service operation is due.*"
S9	**Suggestion: ISPRA should consider specifying in their Package Design Approval Certificates that the date of the next maintenance or servicing operation, according to the approved maintenance or servicing programme, should be indicated on the packaging.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Based on the authorization procedure for carriers ISPRA has collected data on all performed shipments of radioactive material in Italy since 1987. A very comprehensive, web-based database has been developed (TRARADWEB) which contains not just statistical data (e.g., consignor, consignee, transport route, time, …) but also very detailed safety related information (e.g. package type, radionuclides, activity amount, dose rates, …) and which is updated regularly. This modern tool contains options for verification and control of transmitted data (identification of non-compliances) as well as for analyses necessary for statistical and also safety related purposes (e.g. dose assessments for workers and the public, regional information for emergency preparedness and planning).	
(1)	**BASIS: SSR-6 para 308 states that** "*The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the Basic Safety Standards.*"
(2)	**BASIS: TS-G-1.5 para 4.51 states that** *"The competent authority is required to arrange for periodic assessments to evaluate the radiation dose to workers and to member of the public due to the transport of radioactive material. Data from consignors and carriers that need to assess the dose arising from their transport operations may be used in such assessments of radiation doses by the competent authority."*
GP2	**Good Practice: The development, maintenance and use of the comprehensive ISPRA web-based database (TRARADWEB) is considered to be a good practice because it goes beyond the collection of standard transport data by providing additional safety related data and corresponding analyses tools necessary to perform dose assessments due to transport, to identify non-compliances and to support the provincial emergency preparedness and planning.**

5.7. SUMMARY

The system of authorization is rather complex in the Italian system, involving both national and regional authorities. Particular focus has been given to decommissioning, waste management and the planning of a waste repository, which constitute the main challenges for Italy. The

IRRS team identified areas for improvements to better align authorization procedures with the IAEA safety standards and for taking into account international best practices. In the area of radiation sources and transport of radioactive material, definition of the responsible authorities, the application of a graded approach and the coordination between the authorities are among the issues the IRRS team has identified possible improvements. Finally, the development, maintenance and use of the comprehensive ISPRA web-based database (TRARADWEB) is considered to be a good practice.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The existing legislative framework sets out among others provisions for the review and assessment of facilities and activities, in accordance with a graded approach. ISPRA performs review and assessment of relevant information for determining whether the applicant for authorization or the authorized party complies with applicable safety requirements and conditions for authorization. Any licence/authorization issued by the Minister of Economic Development is based on the technical advice and specifications issued by ISPRA, after the analysis of the requested documentation provided by the applicant. The Minister of Economic Development is not allowed in modifying the specifications provided by ISPRA which are binding by law.

The IRRS team reviewed the regulatory review and assessment activities in all the areas covered by the ISPRA oversight. The IRRS team was informed that the review and assessment of ISPRA are performed both before the issuing of an authorization, through the technical evaluation of all the documents provided by the applicant, and by a new technical evaluation when a modification or new activity is to be performed in the facility. In most cases clarifications and additional information are requested to the licensee.

The IRRS team observed that while some technical guides are available for review and assessment, guides on some important facilities and activities as decommissioning of nuclear facilities and radioactive waste management activities and facilities including disposal have to be updated or are under development as reflected in the Module 9. While for radiation sources such technical guidance are still not in place.

The IRRS team was informed, as reported in Module 4, that a draft procedure for review and assessment of nuclear facilities is available and applied to regulate the internal review process based upon experience and expertise of the regulatory staff.

The review and assessment is systematically done taking into account priorities and with a depth commensurate according with a graded approach. The timing is influenced by the short number of experts available.

The IRRS team was informed that any modification that affects safety of a facility or activity is subjected to a notification or to an authorization according to their relevance. In both cases an assessment is conducted by the competent regulatory authority. The management of modifications is regulated by art. 6 of the Act No. 1860/1962 for nuclear installations.

Technical Guide No.2 describes the procedure on how to treat the different types of modifications. It is the same process adopted for original authorization but limited to the part of the plant affected by the modification.

In the areas of decommissioning and radioactive waste management it was noted that the results of reviews and assessment are recorded in a technical report which is prepared by ISPRA for these licensing processes and contains the description and the conclusion of the performed assessment for each one of the addressed aspects. This technical report is the bases (justification) for regulatory decisions as well as tracking of the review and assessment process and document control system. Nevertheless, it should be noted that the review and assessment process in other areas, such as facilities Type A, the situation is different. The review and assessment of the license application for category A sources is not documented in a specific

supporting report by ISPRA while basis for the authorization are provided in the advice to the licensing authorities The results of the review form eventually the basis for the advice and proposed licensing conditions of ISPRA. This issue is addressed in Recommendation R19 in this section.

The IRRS team was informed that observations provided by other administrations involved are considered in the review process. The IRRS team was informed that the radiation risk is the key factor considered in conducting the review and assessment according to a graded approach. Some priorities can be assigned in relation to the interdependency existing with other activities having relevance to nuclear and radiation safety.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The review and assessment of information is performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization. Some of the stages in the lifetime of a facility or the duration of an activity may require specific hold points at which separate authorizations are required. In such cases, the completed stages must be subject to review and assessment, with account taken of feedback from the previous stages.

The IRRS team was informed that ISPRA performs an assessment of all radiation risks prior to the operation, by assessing the analytical study of the radiological impact to the population and workers during normal operation and in case of accidents. During the lifetime of a facility or the duration of an activity by regular inspections and by assessing periodic reports that the authorized parties are requested to submit. To implement these responsibilities ISPRA need to have available internal manpower and organizational arrangements for the review and assessment for all types of facilities and activities supervised. Currently ISPRA does not have sufficient number of competent staff in several areas of review and assessment for all types of facilities and activities.

In the current situation, even if there may be available external independent human resources for review and assessment, including cooperation at international level, ISPRA do not have the needed financial resources to contract such outsourcing services or capacities. In the Action Plan it has been highlighted that the access to technical independent support for review and assessment has to be ensured when needed.

About category B sources, ISPRA is not involved in the review and assessment of the license application. The IRRS team was informed that it is common practice to set up a local committee, involving all advice-giving authorities, to assess the license application of category B sources or facilities. Since the IRRS mission did not include specifically a review of the local competent authorities, no information has been obtained on how detailed this review is performed by these advisory bodies or committees.

The IRRS team was informed that ISPRA has internal capability to use computer codes to assist in its reviews of the potential exposure and occupational exposure dose assessment results obtained by the operator for the in operation in the country facilities and activities. However, ISPRA recognises that it does not currently have the necessary competences or resources for to undertake independent modelling, review and assessment of disposal facilities.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

Prior to the granting of an authorization, the applicant is required to submit a safety assessment, which currently is reviewed and assessed by the regulatory body. The IRRS team noted that ISPRA does not have issued relevant regulation/guidance for safety assessment by the applicants for different types of activities or facilities. This will, among other things, improve the consistency in regulatory requirements on safety assessment.

In this regards it is important the relevant operating experience that can be considered in the safety assessment. For an integrated safety assessment, the regulatory body has to first organize the results obtained in a systematic manner. It has then to identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Currently feedback information is not systematically provided to the authorized party. This includes operating experience from the actual facility or activity, where available, and operating experience from similar facilities and activities. The results of the safety assessment, operational and non-normal operational situations as well as lessons learned from the regulatory monitoring of compliance with safety requirements is not collected, reviewed and systematized by ISPRA as important inputs or the safety assessment of similar facilities.

It should be noted that ISPRA identified this weakness in the developed action plan. ISPRA is planning to "Develop procedures for implementing and using operational and regulatory experience feedback" at the end of 2017.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team noted that ISPRA has not issued regulation/guidance for how to perform safety assessment of activities and facilities involving exposure to ionizing radiation.	
(1)	**BASIS: GSR Part 4 Requirement 2 states that** *"A safety assessment shall be carried out for all applications of technology that give rise to radiation risks; that is, for all types of facilities and activities."*
(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."*
R18	**Recommendation: The regulatory body should establish specific requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct appropriate safety assessments.**

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The IRRS team was informed that during the review and assessment all the relevant factors related to nuclear and radiation safety is considered. The organizational structure of the competent regulatory authority has always had a section devoted to the performance of integrated system analysis, specific devoted to ensure the completeness of the performed assessment and the proper treatment of interfaces and interdependency of the different aspects of nuclear and radiation safety. The radiation risk related to each facility is considered to define

the type and extent of the review and the conducted review and assessment. Risks unrelated to radiation, like fire hazard or others, are considered and analysed in a specific document submitted by the applicant and assessed by the competent Regulatory Authority. In relation to decommissioning activities also interfaces with industrial risk related aspects are requested to be discussed in the application documents (e.g. Plans of Operation).

Internationally it is recommended (GSR Part 4, Requirement 21) that the operating organization is to carry out an independent verification to increase the level of confidence in the safety assessment before it is used by the operating organization or submitted to the regulatory body.

At present ISPRA is performing the verification of comprehensiveness and quality of safety assessment submitted by the applicants or licensees as part of the regulatory review. There are no organized independent regulatory audits for all operators mainly due to the lack of sufficient staff in ISPRA. When it is needed for the review of the presented safety assessment by the operator, ISPRA is organizing technical control visits for clarifying identified aspects in the safety assessment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team observed that, internal formalized procedures are not established by ISPRA for the review of safety assessments and other safety documentation presented in support of an application for authorization.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 24, 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."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 24, para 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory."*
(3)	**BASIS: GSR Part 1 (Rev.1) Requirement 26, para 4.48 states that** *"The regulatory body shall record the results and decisions deriving from reviews and assessments, and shall take appropriate action (including enforcement action) as necessary. The results of reviews and assessments shall be used as feedback information for the regulatory process."*
(4)	**BASIS: GSR Part 1 Requirement 32 states that** "*The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
R19	**Recommendation: The regulatory body should establish formalized procedures to specify the principles, requirements and associated criteria for safety upon which its regulatory review and assessment is performed and for recording the results.**

6.2. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

For research reactors, the safety assessment as well as the regulatory review and assessment are related to their operation or decommissioning because no new reactors are envisaged to be built. Documents supporting applications for modifications or periodic review reports have to be assessed.

In the first phase of the review and assessment of the documents submitted by the applicant or the authorized party, the completeness and the general quality of the documentation is verified by ISPRA in relation to the standard content established in the legislation, technical guides and specifications attached to the authorization. In case of no compliance, specific requests are addressed to the counterpart.

Review and assessment is conducted through licensee's document analysis, interviews as well as technical meetings. The general approach to review and assessment is usually characterized by a high degree of conservatism and caution. Independent evaluations are conducted by ISPRA experts when the presence of a higher hazard is recognized.

If clarifications or additional information are needed during review and assessment process, there is possibility to obtain them during the inspection or technical control. Inspection findings may constitute a basis for specific additional assessments.

The IRRS team was informed that internal procedures for review and assessment process are the same of nuclear installations, based upon the past practices and experience, and they will be formally issued in the context of the Management Manual under preparation. This issue is addressed in Recommendation R19 above. Nevertheless, the results of the review and assessment process are documented in an internal technical report including the indication of any proposed conditions or and of any control or inspections to be undertaken. The competences of the staff to perform review and assessment have been maintained and developed, mainly based on a on the job training programme.

According to the technical specifications within the research reactor operating licence, a periodic safety review is scheduled for every 5 years. This periodic safety review is based mainly on the monitoring of the plant conditions and propose evaluation of the plant safety in accordance with Code of Conduct for Research Reactors. It was found out that at present not all safety factors are addressed in the periodic safety review. In cases where periodic safety review is not performed the inspector can stop the operation of the research reactor. This issue is addressed in Recommendation R20 below.

The IRRS team was informed that, in the frame to implement the Code of Conduct for Research Reactors a process started in order to implement the PSR in a more systematic and comprehensive way taking into account the review process described in SSG-25, by applying a graded approach.

It should be noted that ISPRA identified this weakness in the developed action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: According to the operating licence a periodic safety review is required every 5 years. However, not all relevant safety factors are addressed in this review. It is based mainly on the monitoring of the plant conditions and the evaluation of plant safety in accordance with the Code of Conduct for research reactors.	
(1)	**BASIS: GSR Part 4, Requirement 24 par. 5.10 states that** *"The safety*

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	assessment shall be periodically reviewed and updated at predefined intervals in accordance with regulatory requirements. Periodic review may need to be carried out more frequently to take into account: *(a) Any changes that may significantly affect the safety of the facility or activity;* *(b) Significant developments in knowledge and understanding (such as developments arising from research or operating experience);* *(c) Emerging safety issues due to a regulatory concern or a significant incident;* *(d) Safety significant modifications to the computer codes, or changes in the input data used in the safety analysis."*
(2)	**BASIS: GSR Part 3, Requirement 13 para 3.35 states that** *"Registrants and licensees shall perform additional reviews of the safety assessment as necessary to ensure that the technical specifications or conditions of use continue to be met."*
(3)	**BASIS: SSG-12, para 3.66 states that** *"Over the full operating lifetime of a nuclear installation, the regulatory body should require the person or organization responsible for the nuclear installation and its activities to provide, when necessary or at appropriate intervals, evidence in the form of a safety review that the nuclear installation remains fit to continue operation. The objective of a safety review in the licensing process is to verify:* *(a) That the nuclear installation adheres to current safety standards and national regulations;* *(b) That the licensing basis remains valid;* *(c) That any necessary safety improvements are identified;* *(d) That the required level of safety is maintained until the next safety review is due for completion;* *(e) That any measures necessary to ensure a high level of safety for the full expected operating lifetime, such as additional monitoring, are implemented.*"
R20	**Recommendation: The regulatory body should require the operators of research reactors to perform periodic safety reviews of all factors of relevance for safety according to a graded approach.**

6.3. REVIEW AND ASSESSMENT FOR TRANSPORT

ISPRA is able to independently review and assess technical data and the results of tests submitted by an applicant for the approvals requested by the IAEA Regulations SSR-6. The independent review and assessment in line with SSR-6 covers all aspects of criticality, heat transfer, radiation protection, structural analysis and all related measures of the management system of the applicant. In case of an application for approval of package design for which a prototype will be subject to the tests, established by the IAEA Regulations SSR-6, the preliminary tests program is discussed with the applicant and a management system is requested that addresses all the aspects of the testing.

There are no internal procedures and guides for review and assessment work available as part of the ISPRA management system (see module 9.6). Presently the technical resources for review and assessment seem to be acceptable due to the current situation that for the existing packages in use only limited review and assessment activities are necessary to prolong existing certificates and to validate foreign certificates. This is no longer the case for the future when new package designs will have to be approved and a full review and assessment work must be performed in compliance with the latest state of art.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In the future, shipments of spent fuel and return shipments of vitrified waste from reprocessing to Italy are expected. Therefore it is essential to maintain and develop the skills of the staff of the competent authority to review, assess and approve package designs for these transports.	
(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 number of facilities and activities to be regulated, to perform its function and to discharge its responsibilities."*
(2)	**BASIS: TS-G-1.5, para 2.13 states that** *"The competent authority should establish and maintain a programme for training its own employees."*
R21	**Recommendation: The regulatory body should establish and maintain an appropriate training and qualification programme to assure that the future needs regarding the review, assessment and approval of package designs for transport of spent fuel and high level vitrified waste are met.**

6.4. SUMMARY

ISPRA is performing the regulatory review and assessment of the safety assessment and other safety documentation provided by the operator in support to the licence application independently. To improve its regulatory functions related to review and assessment, ISPRA should (a) establish specific requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct appropriate safety assessments and (b) develop procedures to specify the principles, requirements and associated criteria for safety upon which its regulatory review and assessment is performed and for recording the results.

For the research reactors, a periodic review report as a licence condition is scheduled every 5 years. The review approach is based mainly on the monitoring of the facility conditions and evaluation of the plant safety in accordance with the Code of Conduct for Research Reactors. Since not all relevant safety factors are addressed in this review, ISPRA should require the operators of research reactors to perform periodic safety reviews of all factors of relevance for safety according to a graded approach.

In the future, shipments of spent fuel and return shipments of vitrified waste from reprocessing to Italy are expected. Therefore, it is essential to maintain and develop the skills of the staff of the competent authority to review, assess and approve package designs for these transports. The regulatory body should establish and maintain an appropriate training and qualification programme to assure that the future needs regarding the review, assessment and approval of package designs for transport of spent fuel and high level vitrified waste are met.

7. INSPECTION

7.1. GENERIC ISSUES

According to the Legislative Decree 230/1995, inspections related to nuclear safety as well as radiation protection of workers and population is performed by ISPRA. In case of infringement of specific rules of the Nuclear Act, Legislative Decrees and license conditions ISPRA inspectors are entitled to report to the public prosecutor of the jurisdiction in which the installation is located.

The Ministry of Health, through its local Health Bodies, is competent for performing inspections related to the protection of the public in relation to nuclear facilities and activities. The Ministry of Labour and Social Affairs, through its local inspectorates, is competent for performing inspections for the protection of workers in relation to nuclear facilities and activities.

7.1.1. INSPECTION PROGRAMME

The inspection programme is developed every year including routine inspections and inspections on specific operations conducted at the facilities. In addition to the planned inspections, reactive inspections are conducted at any time if an unusual event occurs at a nuclear installation or during the conduct of an activity involving the use of ionizing radiation sources. The program is reviewed every six months.

The inspections are generally unannounced. The IRRS team observed that graded approach commensurate with the risk associated with the facilities and activities is not sufficiently reflected within the annual inspection programme taking into account the resources available. ISPRA should further reflect in its programme a graded approach including both announced and unannounced inspections. This issue is addressed in Suggestion S10 below.

Technical controls are also performed by other ISPRA professional staff members with the purpose of achieving data, information and other technically relevant elements to be evaluated with respect to technical regulations.

For authorities (Regional Labor Inspectorate and Regional Sanitary Inspectorate) which are also competent to perform inspection on facilities and activities using radiation sources and investigate the radiation protection aspects there is no evidence that these authorities actually develop a programme of inspections. It is recognized by ISPRA that coordination between the different competent authorities has to be improved.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team was informed that inspections conducted by ISPRA are generally unannounced. ISPRA has an internal plan of inspections, however a graded approach commensurate with the risk associated with the facilities and activities is not reflected.	
(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*

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	the areas and programmes to be inspected, in accordance with a graded approach."
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections, both announced and unannounced."*
S10	**Suggestion: The regulatory body should consider complementing its programme for inspection of facilities and activities so as to better implement a graded approach including both announced and unannounced inspections.**

7.1.2. INSPECTION PROCESS AND PRACTICE

The purpose of inspections is to verify the fulfillment of rules and technical specifications and conditions attached to the license having legally binding relevance.

In case of non-compliances related to the protection of exposed workers (Legislative Decree 230/1995 – Chapter VIII), the regulatory body is entitled to impose corrective actions to the licensee. ISPRA has not implemented a formal procedure to confirm to the authorized party the effective implementation of these actions. However, the procedure to apply the corrective actions is defined in Legislative Decree No 758/1994, articles from 19 to 25, as stated in art. 143 of Legislative Decree No. 230/1995.

The inspection starts with an introductory discussion with representatives from the licensee. Inspectors explain the inspection objectives and the topics and areas that will be verified. Information about the status and conditions of the installation or of ongoing activities is requested.

The inspection proceeds by documents review, site visits, interviews, with operating staff and tests of safety systems. The inspector is responsible for recording the results of the inspection. An inspection report is prepared at the end of the inspection and is countersigned by the licensee.

Inspection reports are archived. These reports are reviewed to reveal possible trends by individual inspectors. A specific procedure in this regard is however not in place.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: During the site visits, the IRRS team observed that inspections are conducted by experienced inspectors using a predefined check lists. The IRRS team has also been informed that documented inspection procedure is under preparation in the framework of the management manual.	
(1)	**BASIS: GS-G-1.3, paragraph 6.1 states that** *"The regulatory body should have a system to audit, review and monitor all aspects of its inspection and enforcement activities… The following points should be considered in this system:* *Procedures in the regulatory body relating to inspection activities such as procedures for planning inspections and for dealing with outstanding*

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	issues."
S11	**Suggestion: The regulatory body should consider implementing defined inspection procedures.**

7.1.3. INSPECTORS

The prerequisite to be an inspector are:

- To be graduated and to be experienced in the appropriate fields;
- To be trained on tools of law and judicial issues (4 days training by the public prosecutor services);
- To be trained on-job by a senior inspector and;
- To pass successfully the evaluation by an internal commission.

When all these criteria are met, the inspector is appointed by an official statement which assigns the inspector's missions and the conditions of revocation (Legislative Decree 230/1995, art.10-2). The appointment is given for 5 years and it is renewable.

At present there are only 5 staff members appointed as inspectors and involved for inspection of all activities and facilities. As a consequence the number of performed inspections is low but in any case the risk associated with these activities and facilities are taken into account (R25). Five staff members are under training. For nuclear installations supervision is also performed by technical controls conducted by other professional staff.

As indicated in the ARM and as confirmed by the interviews performed during the IRRS mission, the competent authority is not provided with adequate human and financial resources to perform a complete inspection programme to ensure that all regulatory requirements are verified. The Government should provide ISPRA with human and financial resources to ensure adequate discharge of its statutory obligation for the regulatory control of safety. This issue is addressed in Recommendation R3 in Module 1 and Recommendation R7 in Module 3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team noticed that the number of inspections performed at facilities and of activities need to be increased. One reason for this is the small number of appointed inspectors and of staff for technical control.	
(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) Requirement 29, states that** *"Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(3)	**BASIS: GSR Part 6 Requirement 5, para 3.3 states that** *"The responsibilities of the regulatory body shall include: ... - Inspecting and reviewing*

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	decommissioning actions and taking enforcement actions in the case of non-compliance with the national legal and regulatory framework, or with the authorization or licence conditions and safety requirements established by the regulatory body."
(4)	**BASIS: GSR Part 5 Requirement 3, states that** *"The regulatory body shall carry out activities to verify that the operator meets these conditions."*
R22	**Recommendation: The regulatory body should develop a plan for increasing the number of staff with the required competencies to be nominated as inspectors, so that inspections of facilities and activities are performed and are commensurate with the associated radiation risks.**

7.2. INSPECTION OF RESEARCH REACTORS

No specific arrangements are reported concerning the inspection program of research reactors. The scope and the frequency of inspections are commensurate with the potential hazard posed by the research reactors. One or two inspections per year and several technical controls are performed yearly.

In case of experiments or test characterized by plant modification, before the implementation, a detailed technical control is performed by ISPRA to verify that the provisions in place are in compliance with the authorization requirements.

Safety culture aspects are usually within the scope of the inspections.

The IRRS team observed an inspection performed at the TRIGA RC 1, Casaccia. The inspection was conducted in a very professional manner and in a good spirit. It was found that the inspection was performed correctly, starting with the entrance briefing. During the inspection the review of maintenance documentations, the compliance of operating parameters with the technical specifications and identification of the deficiency were addressed correctly. The inspection closed with the exit meeting. At the end of the inspection, minutes were prepared and signed by the operator.

7.3. INSPECTION OF WASTE MANAGEMENT FACILITIES

According to the information gathered from ISPRA, in case of waste management facilities, inspections are mainly focussed on the inventory data bases, verification of waste packages status, storage capacity, operation of required systems, storage conditions, measurements of surface contamination and doses rates inside and outside the stores. These are the inspection topics as well as in the radioactive waste management systems of the nuclear facilities being decommissioned.

The IRRS team observed a regulatory inspection carried out by ISPRA to the waste management facility operated by Nucleco at Casaccia. SOGIN is the owner of the majority of wastes in Italy, particularly those from the NPPs. Institutional wastes received at the site are owned by ENEA. The facility receives wastes for treatment, conditioning, packaging and storage. The IRRS team was informed that after packaging the wastes from the NPPs are routinely transported back to the NPPs for storage, owing to the concerns of local residents.

The materials received include also disused sealed radioactive sources and other institutional wastes from other private collectors and those materials and waste remain in storage at the Nucleco facilities.

During the inspection written records, the super-compaction and temporary waste storage facilities were inspected.

After the inspection of the facilities, further checks were made of the documented results of the health physics measurements made during the site inspection and of the records of routine activity measurements inside the long-term store.

7.4. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Currently, only one staff member of ISPRA is entitled to conduct inspection on radiation sources. The inspection is always performed by the inspector assisted by a staff member.

Regarding the radiation sources, for facilities and activities an annual programme is set up by the inspector in charge. The number of planned inspections usually ranges from 8 to 15 inspections (more or less equally dispatched between category A and category B sources). Because of the lack of human resources, the number of programmed inspections is not commensurate with the number of authorizations granted (91 category A licenses and 1500 category B licenses) and does not permit to control the facilities and activities with an adequate frequency. Building up the programme, for category A, being considered to have among them a comparable level of risk, the selection of sites to be inspected is mainly done according to the date of the last inspection. For category B the different level of risk is taken into account.

The IRRS team observed an inspection performed at the Gemelli hospital on a cyclotron facility. The inspection was conducted in a very professional manner and in a good spirit. The authority of the inspector is obviously recognized by the licensee. The inspector starts by a short introduction of the agenda of the day and of the scope of the inspection, which was mainly the verification of the implementation of the specific conditions prescribed by the licence, according the prepared check-list. Then a review of the following documents was performed:

- Records of individual dosimetry and medical supervision of exposed workers,
- Qualified expert's report of technical radiation protection controls.

The site visits of the cyclotron installations gave the opportunity to conduct staff interviews, to perform safety devices tests and to check the records of the operations.

7.5. INSPECTION OF DECOMMISSIONING ACTIVITIES

According to the information from ISPRA, in case of nuclear facilities under decommissioning the inspections are mainly related to checks of ongoing operations and their compliance with the approved Detailed Project or Plans of Operations envisaged in the decommissioning license. Waste management activities are also taken into account with the focus on the waste produced during the dismantling and other activities. The environmental program is verified as well.

The IRRS team visited the Garigliano NPP (one of three NPPs under decommissioning) to observe an inspection implemented by ISPRA. The main topics of the inspection were checking of the examples of data of stored radioactive waste drums with the data contained in the files. This inspection revealed an inconsistency in the case of one drum, which did not constitute a deviation from the requirements. The ISPRA inspector along with the inspection via a

telephone call was consulting with an expert of the competent authority on its finding to exactly define its safety significance. It is remarkable that the inspector used the hardcopy data for verification which is not a simple activity. The inspection was executed basically according to the plan. The revealed minor incoherence of data will be clarified by the operator on the decision of the inspector. It will be included into the inspection report to be completed shortly after the inspection. In parallel with the inspection, the IRRS team could observe a technical control activity.

7.6. INSPECTION OF TRANSPORT

The inspections are generally performed on the premises of the consignor or consignee during the operations of transport of fissile or non-fissile material. The basis for the inspection is usually the compliance with the relevant transport requirements based upon the IAEA Regulations SSR-6 and the modal regulations (ADR, RID, ADN, IMDG Code and ICAO TI). These inspections also include transport packages and transport operations. The inspections are also dedicated to the evaluation of the radiation protection programme of the consignor/carrier to verify compliance with the requirements both of IAEA Regulations SSR-6 and the Radiation Protection Act (Legislative Decree 17 March 1995, No. 230).

In particular due to the missing legal assignment to ISPRA as the competent authority for transport of radioactive material (class 7) for all modes of transport inspections during shipment cannot be performed (see Module 9.6). In this regard the draft action plan of the counterpart has identified already an appropriate action for road transport.

ISPRA has not sufficient human resources to perform all necessary inspections to ensure that all regulatory requirements that are important to safety are correctly fulfilled in practice. This issue is addressed in Recommendation R3 in Module 1, like

- manufacturing of packages which are not subject to competent authority approval (majority of packages in use in Italy),
- maintenance, repair and service activities for packaging,
- routine inspections during transport and measurement campaigns.

It was found out that for packages which are not subject to competent authority approval, compliance with the applicable requirements of SSR-6 is demonstrated by inspection, for which the consignor must provide documentary evidence. For this purpose the consignor is using a certificate of compliance, for which some important information is missing. This issue is addressed in Suggestion S12 below.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: For packages which are not subject to competent authority approval, compliance with the applicable requirements of SSR-6 is checked by inspection. In order to provide documentary evidence, the consignor is using a Certificate of Compliance. However, as observed by the IRRS team, some important information is missing in this certificate.	
(1)	**BASIS: SSR-6, para 801 states that** *"For package designs where it is not required that a competent authority issue a certificate of approval, the consignor shall, on request, make available for inspection by the relevant competent authority, documentary evidence of the compliance of the package design with all applicable requirements."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: SSG-26, para 801.3 states that** *"In the case of packages that do not require competent authority approval, some form of 'certificate of compliance' should be applied. Such certificates of compliance should include the following information: (a), (b), (c), … , (m)."*
S12	**Suggestion: The competent authority should consider reviewing the consignor's Certificate of Compliance for consistency with the IAEA safety standards.**

7.7. SUMMARY

According to the Legislative Decree 230/1995, inspections are performed by ISPRA. Annual work plans are prepared to carry out inspections for facilities and activities. The regulatory body inspection staff is well knowledgeable. However, the human resource issues need to be addressed. The IRRS team found that the regulatory body should further develop procedures for inspection and an inspection programme.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The Legislative Decree No. 230/1995 establishes the regulatory framework for the enforcement process and enables the licensing authorities to suspend or revoke the authorizations if necessary.

According to the same decree, in performing their functions, the ISPRA inspectors are judicial police officers. As such, they are required, under the law, to document any non-compliance to the Nuclear Act or to the specific licence conditions in the inspection report. These non-compliances are considered as criminal offences and must be reported to the public prosecutor.

For violations regarding workplace safety, the Legislative Decree 758/1994 introduces a particular mechanism to downgrade a criminal offence to an administrative offence, provided that the specific dispositions required as corrective actions to the offender are fulfilled and the fine is paid.

In case of non-compliances related to the protection of exposed workers (Legislative Decree 230/1995 – Chapter VIII), the regulatory body is entitled to impose corrective actions to the licensee. The IRRS team was informed that the procedure to apply the corrective actions is defined in Legislative Decree 758/1994, articles from 19 to 25, as stated in art. 143 Legislative Decree 230/1995.

8.2. ENFORCEMENT IMPLEMENTATIONS

The IRRS team was informed that in the case of a non-compliance, which is not covered by the Legislative Decree 758/1994, the enforcement process is managed by the public prosecutor. Anyway, the article 55 of Penal Code oblige inspectors, as police officer, on their own initiative, to take the news of violations, prevent them from being taken to further consequences, investigate the authors, take the steps necessary to ensure the sources of evidence and collect whatever can serve for the application of law.

The authority which has issued the licence can theoretically suspend or revoke it. In practice, the Ministry of Economic Development has never suspended an authorization.

In case of a violation the inspector has to report to the prosecutor. From that moment he cannot manage the non compliance according to a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team has been also informed that in the case of a non-compliance, which is not covered by the Legislative Decree 758/1994, the enforcement process is managed by the public prosecutor and the regulatory body has no control on the corrective actions implementation. As such, the enforcement measures are not always commensurate with the associated risk.	
(1)	**GSR Part 1. Requirement 31, para 4.54 states that** *"The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	approach.
S13	**Suggestion: The Government should consider attributing further enforcement powers to the regulatory body in order that the response to the non-compliances, is in accordance with a graded approach.**

8.3. SUMMARY

The Legislative Decree 230/1995 and the Legislative Decree 758/1994 provide the regulatory body with the legal basis to carry out enforcement actions. As stated in section 8.1 there are documented enforcement rules to define the criteria to implement the Legislative Decree 758/1994 provisions. As such, the enforcement measures are not always commensurate with the associated risk.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

To facilitate compliance with regulatory requirements, the regulatory body should issue guidance as part of the management system. Such guides should be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experienced gained. It has been found that for all the following areas (9.2 – 9.6) appropriate guides and procedures for their implementation are missing. This issue is addressed in Recommendation R11 in Module 4.

It has been observed that according to the 7th National Report under the Convention of Nuclear Safety the legislative system does not contain specific provisions regarding quality assurance in nuclear installations. Quality assurance requirements are detailed in specific technical guides issued by the regulatory authority in 70's and 80's. However, the existing requirements related to the quality assurance are not in line with the nowadays valid IAEA Safety Standards related to the management systems. The IRRS team was informed that a new guide regulating the management system of the licensee has been drafted to be issued in the context of the ISPRA updating programme of Technical Guides.

The IRRS team was informed that technical guides on decommissioning and waste storage facilities are based upon internationally agreed standards are under preparation. In the case of decommissioning the standard content of decommissioning project and plans of operations is detailed in the specifications attached to the licence.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ISPRA has no processes in place for adopting, promoting and amending its technical guides according to changes resulting from internationally agreed standards or the feedback of operational lessons learned.	
(1)	**BASIS: GSR Part 1(Rev.1) Requirement 34, 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. Moreover, technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides."*
R23	**Recommendation: The regulatory body should develop and implement processes for establishing, adopting, promoting and amending guides.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: There are no detailed and updated guidance on the format and content of the documents to be presented as part of the application for authorization for approvals.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(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. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."*
(2)	**BASIS: GSR Part 5 Requirement 3, para 3.8 states that** *"To facilitate compliance with regulatory requirements, the regulatory body has to do the following: Provide necessary guidance on the interpretation of national standards and regulatory requirements that takes into consideration the complexity of the operations and the magnitude of the hazards associated with the facility and operations;."*
(3)	**BASIS: GSR Part 6 Requirement 5 states that** *"The regulatory body shall also take actions to ensure that the regulatory requirements are met."*
(4)	**BASIS: SSR-5 Requirement 2, para 3.8 states that** *"The regulatory body has to provide guidance on the interpretation of the national legislation and regulatory requirements, as necessary, and guidance on what is expected of the operator in respect of each individual disposal facility."*
(5)	**BASIS: GSR Part 6 Requirement 11, para 7.9 requires that** "*A final decommissioning plan shall be submitted to the regulatory body for approval.*"
(6)	**BASIS: GSR Part 6 Requirement 11, para 7.10 requires that** "*The final decommissioning plan and supporting documents shall cover the following: the selected decommissioning strategy; the schedule, type and sequence of decommissioning actions; the waste management strategy applied, including clearance, the proposed end state and how the licensee will demonstrate that the end state has been achieved*."
R24	**Recommendation: The regulatory body should complete the issuing of specific guidance on the content of the documents to be submitted by the applicant in support of an application for authorization for decommissioning, radioactive waste management including disposal, research reactors, transport, radiation source facilities and activities.**

9.2. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

At present, five research reactors are in operation with authorizations based on the legislation from 1962. The regulatory framework for research reactors is the same as for nuclear power plants. It covers the detailed site selection and evaluation requirements including criteria for site evaluation. The adequacy of the design of research reactors (RR) are verified in the authorization process as required by Legislative Decree No. 230/95. There are no specific and detailed requirements for the design conditions for RR. The requirements for design are adopted case by case. The approach widely used in the past was to refer to the regulations of

the country of origin. In the legislation there is the provision of a simplified licensing process for research reactors with a thermal power lower of 100 kW.

With respect to the content and depth of the Safety Analyses Report (SAR), the general rule is the same provision as applied for Nuclear Power Plants (NPP). The regulatory framework includes the requirements for Operational Limits and Conditions of RR.

According to the technical specifications conditions established in the operating license for RR, a periodic safety review is scheduled every 5 years, with an approach based mainly on monitoring the safety performance of the installations.

The question of training of any person working in the facility is also addressed. For nuclear installations, including RR, the Legislative Decree requires a document named "Operating Rules" in which the organizational structure for the management of the installation is defined, with regard to both normal and accident conditions. Such a document and its modification is approved by ISPRA.

The licensee is required by Legislative Decree No. 230/95 to set up a plant Safety Committee for RR, which has the responsibility to assess any decisions or changes with safety relevance to the facility. The composition of the Safety Committee is required by law and has been approved by ISPRA.

Technical guides set up technical criteria to be taken into account by operators in the siting of nuclear installations, submission of specific projects for approval, conduct of operations as well as rules of good practice. During the discussion it was found out that internal procedures for systematically review of the guides in accordance with the new requirements are currently not in place. The regulatory body should consider action plan, based on the gap analysis, for new Technical Guides, needed on the area of nuclear safety of RR. This issue is addressed in Recommendation R23. Additionally, it was found out that the existing set of technical guides do not cover all areas of the nuclear safety for nuclear facilities. The regulatory body should consider action plan, based on the gap analysis, for new technical guides, needed on the area of nuclear safety of RR. This issue is also addressed in Recommendation R23.

It was found out that no requirements for aging management program and use of feedback from operating experience for RR are in place. RB should establish requirements on RR operational programmes for ageing management program and the operating feedback programme. This issue is addressed in Recommendation R25.

Developing the technical guide on safety requirements for operation and periodic safety review was also highlighted in the Action Plan for the IRRS Mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team observed that specific requirements are not established for ageing management program and use of feedback from operating experience for research reactors.	
(1)	**BASIS: SSG-12, para 3.59 states that** *"The 3.59. The following are operational programmes that the licensee should have in place before and during operation. The regulatory approach to reviewing, assessing and inspecting such programmes should be graded according to the type of nuclear installation and its activities. Such programmes may be subject to approval by the regulatory body, as appropriate:* *(u) Ageing management*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(w) Feedback of operating experience."
(2)	**BASIC: SSG-10, para 3.8 states that** *"In practice, the ageing management programme at a research reactor is accomplished by coordinating existing programmes, including maintenance, periodic testing and inspection programmes, as well as applying good operational practices, research and development (of material behaviour, radiation effects, chemistry, etc.), and incorporating lessons learned from operating experience."*
(3)	**BASIS: SSR-3, Requirement 37 states that** "*The design life of items important to safety at a research reactor facility shall be determined. Appropriate margins shall be provided in the design to take due account of relevant mechanisms of ageing, such as neutron embrittlement and wear-out, and of the potential for age related degradation, to ensure the capability of items important to safety to perform their necessary safety functions in operational states and accident conditions in case of demand throughout their design life. The life cycles of the technology utilized and the possible obsolescence of the technology shall be considered."*
R25	**Recommendation: The regulatory body should establish requirements on research reactor operational programmes for ageing management and for the use of feedback from operating experience.**

9.3. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The Director General of ISPRA ordered in February 2013 to elaborate 3 Technical Guidance documents (on safety criteria of temporary storage facilities of radioactive waste, on safety criteria of decommissioning activities of nuclear installations, and on criteria and process of release from regulatory control of materials, nuclear installations and sites containing radioactive nuclides) nominating in parallel participants of 3 workgroups for this tasks. The draft guidance documents were elaborated in the same year, but generally lacking of human resources, defined actualised procedure on internal and external review process, as well as on steps of finalising the drafts, these guidance documents were not issued up to now.

In general, most technical guidance were issued a long time ago. The IRRS team was informed that the selection of guides to be reviewed or prepared has been based on priorities defined taking into account need associated to the current national programme (Decommissioning and waste management activities). One new guide related to the siting criteria of National Repository was issued in the last years.

SSR-5 provides requirements on the disposal of radioactive waste. The self-assessment conducted by the regulatory body acknowledges in Section 5 (the Module on Safety Requirements for Disposal of Radioactive Waste) that many of the requirements contained in SSR-5 are not yet incorporated into the Italian regulatory framework. However, the self-assessment conducted also explains that a Technical Guide is being prepared that will address these gaps.

The regulatory authority's draft Action Plan identifies a future activity to "*Develop a technical guide on safety requirements for construction and operation of a near surface disposal facility*".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The self-assessment of ISPRA and the team findings show that international safety requirements contained in the IAEA safety standards on radioactive waste management and decommissioning are not yet incorporated into the Italian regulatory framework. The IRRS team was informed that a series of technical guides, that will address these gaps, is being prepared.	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which regulatory judgements, decisions and actions are based."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 34 para 4.62 states that** *"The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.*
(3)	**BASIS: GSR Part 5 Requirement 3 states that** *"The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities and shall set out procedures for meeting the requirements for the various stages of the licensing process."*
(4)	**BASIS: GSR Part 6 Requirement 5 states that** *"The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met."*
(5)	**BASIS: SSR-5 Requirement 2 states that** *"The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met."*
R26	**Recommendation: The regulatory body should complete the existing requirements for decommissioning and should update and/or establish the requirements for radioactive waste management facilities and activities, including disposal.**

9.4. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

In the area of radiation sources, technical guides have been issued in the past with regard to the licensing procedure. With the transposition of the EC Directive 96/29/Euratom, those guides were integrated into the annexes of Legislative Decree 230/95. Since then, new technical guides setting up detailed requirements were not developed. This issue is addressed in Recommendation R24 above.

ISPRA has not developed internal guides to support its regulatory work. Consistency of the approach within the regulatory body is globally ensured through regular exchanges and close cooperation of the involved personnel. With regard to the licensing authorities for category B radiation sources and with regard to the regional inspectorates, the lacking of clear procedures contributes however to the inconsistency of approaches as identified through Recommendation R15 in Section 5.4.

According to Legislative Decree 230/95-art.29-2, regions and autonomous provinces have to establish regional laws for the establishment of the competent licensing authority and inspectorate in the area of radiation sources used for medical proposes.

The representatives from the Ministry of Health emphasized that they have no power to review the fulfillment of the regulatory control of the regional authorities.

The register of the radiation sources, as defined by Article 9, para 1 of Legislative Decree -52, has not been established, as already highlighted in the Action Plan for the IRRS Mission.

It is to be noted that Italy has not yet politically committed to the guidance on the import and export of radioactive sources.

9.5. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

ISPRA explained to the IRRS team that technical guidance documents are currently under development. A service order signed in February 2013 by the General Director of ISPRA assigned to some experts of ISPRA (Nuclear section) to develop the three following technical guides:

- on the safety criteria for interim storage facility;
- on the safe decommissioning of nuclear installations;
- on clearance levels for radioactive materials.

The process to develop such documents foresees that the draft technical guides shall be submitted to internal review process prior to their issuance for external consultation.

The technical guide on decommissioning has been drafted in December 2013, updated on the basis of the last version of the WENRA SRLs of 2015, and submitted to an internal review process.. The technical guide on decommissioning provides also an annex listing the documents to be submitted to the regulatory body. This issue is addressed in Recommendation R26 in Section 9.3.

9.6. REGULATIONS AND GUIDES FOR TRANSPORT

Italy as contracting party of international agreements or conventions which apply for international transport of dangerous goods including radioactive material, the international regulations for the different modes of transport respectively ADR (road), RID (rail), ADN (inland waterway), IMDG Code (sea) and ICAO TI (air). The transport requirements of the IAEA Regulations SSR-6 are fully implemented into the international modal regulations and

transposed into the national regulatory framework by appropriate Decrees and EC Regulations for land transport (road, rail, inland waterway), sea transport and air transport.

Other than the regulations for transport of dangerous goods the transport of radioactive material is also regulated by the legislative and regulatory framework for the peaceful use of nuclear energy and for the activities with the use of ionizing radiations mainly constituted by:

- Act on peaceful use of nuclear energy - Law 31 December 1962, No. 1860 (as modified);
- Radiation Protection Act - Legislative Decree 17 March 1995, No. 230 (as modified).

Article 5 of the Law No. 1860 establishes that transport of radioactive material for all modes of transport has to be carried out by authorized carriers. That authorization is issued by the Ministry of Economic Development and countersigned by the Ministry of Infrastructure and Transport. Article 21 of the Radiation Protection Act establishes that the carrier authorization has to be issued on the basis of a technical advice of ISPRA and of the Ministry of Interior, expressed after the review and assessment of the applicant's documentation. The technical advice of ISPRA takes into account also some aspects of the IAEA Transport Regulations SSR-6.

It can be concluded that in Italy the regulations for safe transport of radioactive material as implemented in the dangerous goods transport regulations of class 7 are in full compliance with the requirements of SSR-6 for all modes of transport but that appropriate guidelines on how to implement these requirements in the various fields of transport are missing. The draft action plan of the counterpart has identified already an action to develop a technical guide on approvals.

Although ISPRA is acting as a competent authority as defined in SSR-6 there is currently no legal assignment to ISPRA to perform this function for all modes of transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ISPRA acts as the competent authority for all functions as required by the IAEA Transport Regulations SSR-6, but these roles and functions are not assigned to it.	
(1)	**BASIS: SSR-6 para 207 states that** *"Competent Authority shall mean anybody or authority designated or otherwise recognized as such for any purpose in connection with these Regulations."*
(2)	**BASIS: TS-G-1.5 para 2.6 states that** *"The responsibilities and duties of the competent authority (regulatory body) are required to be defined within the national legal framework of a State, in accordance with the requirements established in GS-R-1."*
R27	**Recommendation: The Government should assign the competent authority for all modes of transport of radioactive materials and define the responsibilities and duties in the national legal framework as required in the IAEA Transport Regulations SSR-6.**

The IRRS team observed that a documented management system does not exist which is commensurate with ISPRAs functions and tasks to be performed as competent authority for transport to assure compliance with the IAEA Transport Regulations SSR-6 including the following areas:

- Procedures for package design and shipment approvals
- Conducting safety reviews and safety assessments
- Issuing approvals
- Carrying out regulatory inspections and any necessary enforcement actions (inspection programme, inspection checklist and enforcement programme)
- Development of technical guides for applicants for package design and shipment approvals
- Distribution and publication of information related to the safe transport of radioactive material

This issue is addressed in Section 4.2 Recommendation R11. This was also highlighted by the counterpart in the preliminary Action Plan for the IRRS Mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team observed that a procedure at national level which allows a systematic review and revision of the transport regulations to keep them up to date, to take feedback from experience into account and to involve all interested parties is currently not in place.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and of relevant experienced gained."*
R28	**Recommendation: The Government should establish a systematic process for reviewing and revising transport regulations to keep them up to date, in which feedback is taken into account and interested ministries and competent authorities establish a consultation process with organizations representing applicants and users within the field of safe transport of radioactive material.**
S14	**Suggestion: The Government should consider establishing a national advisory committee to perform the review and revision processes.**

9.7. SUMMARY

There is in general a lack of appropriate and up to date technical guides in various areas. The IRRS team was informed that some gaps are going to be filled through some guides under preparation on priority topics related to the national program (waste management and decommissioning). It is recommended that within the management system of the regulatory body procedures should be put in place which assure that in all areas relevant guides are developed, adopted, promoted and amended and reviewed as needed to keep them up to date and to take feedback from experience into account.

In the field of radiation sources, recommendations have been provided to enable regional authorities to have consistency in the regulatory control over category B sources and to develop technical guides for defining criteria for safety applicable to facilities using radiation sources.

For research reactors it is recommended to develop and implement requirements for an ageing management programme and operating experience feedback programme, which are not available so far.

The transport regulation, are fully consistent with the IAEA Transport Regulations SSR-6 but for its full implementation in practice a clear legal assignment to ISPRA as competent authority for all modes of transport in this field, is missing and must be put in place.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

The self-assessment was prepared based on the IAEA Safety Standard GS-R 2; however the review was performed according to the recently published the IAEA Safety Requirements GSR Part 7, superseding the GS-R-2.

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Roles and responsibilities in emergency preparedness and response

The basic legal framework in Italy for EPR is established in the following documents:

a) Act of 24 February 1992, No. 225, which establishes the current National Service of Civil Protection;

b) The Legislative Decree No. 230 of 17th March 1995 and its subsequent amendments;

c) Decree of the Presidency of Council of Ministers of 10th February 2006: "Guidelines for emergency planning in port areas affected by the presence of nuclear powered ship (in implementation of Article 124 of Legislative Decree no. n. 230, 17 March 1995, 1995);

d) Decree of the Presidency of the Council of Ministers of 10 February 2006 "Guidelines for emergency planning for the transport of radioactive and fissile material (in implementation of Article 125 of Legislative Decree No. 17 March 1995, n.230 and subsequent amendment");

e) Decree of the Presidency of Council of Ministers of 19th March 2010 approving the National Plan of the Protective Actions Against the Radiological Emergencies;

f) Legislative Decree 6 February 2007 No. 52 (provisions for emergency situations with orphan sources);

g) ISPRA Technical Guide N.21 "Content of the Operating Rules";

h) Technical provisions annexed to the issued licenses/authorizations;

i) Decree of the Ministry of Health 26 January 2009;

j) Other relevant regulation relating other response organizations.

The emergency management system established in Italy is coordinated at the national level by the Department of Civil Protection of the Presidency of the Council of Ministers and at the local (provincial) level by the Prefect of the province.

According to the Legislative Decree no. 230 of 17th March 1995 and subsequent amendment and to the national and off site emergency planning, ISPRA is responsible for:

a) assuring that the operating organization establishes on-site EPR arrangements based on the threat (hazard) assessment;

b) guaranteeing that any authorized activity cannot be initiated before such arrangements, as well as the off-site emergency plan, are in force;

c) performing regulatory oversight, attending to the emergency exercises and other activities the operating organization shall play on a regular base in compliance with the technical prescriptions attached to the authorization;

d) performing the safety assessment of nuclear facilities that together with the safety analysis elaborated by the licensee, constitute the threat (hazard) assessment on which the on-site and off-site emergency plans are prepared;

e) acting as a notification point for international early notification system and off-site emergency plans of nuclear installation and nuclear powered vessels ;

f) supporting the National Department of Civil Protection in elaboration of the National Radiological Emergency Plan by providing at national level the threat assessment of postulated accidental events at foreign NPPs located within 200 km from the national borders;

g) providing technical advice to the off-site emergency authorities as provided by the off-site emergency plans by sending a liaison officer to the local off-site emergency centre, and activating the ISPRA Nuclear Emergency Centre;

h) providing advice to the national civil protection authorities in case of activation of the National Radiological Emergency Plan;

i) coordinating the Committee for data analysis and radiological assessment (CEVAD - Data Processing and Evaluation Centre) for advising the emergency management authorities about the protective actions to be taken and the public information to be provided;

j) coordinating the national network of the regional laboratories for the surveillance of the environmental radioactivity;

k) advising for the establishment of intervention levels and operational intervention levels;

l) performing the threat assessment for the emergency planning process concerning accidents occurring at an NPP abroad, at a nuclear-powered vessel in an Italian harbour or during transport of radioactive material (other than spent fuel);

m) support the off-site emergency authority in the preparation the off-site emergency planning.

ISPRA's two different roles in EPR, as regulatory authority and also as a response organization and the stemming functions, have been addressed during the IRRS review.

Responsibilities of operators of the facilities listed below are established by the legislation:

a) Nuclear facilities, including facilities for management of spent fuel;

b) Facilities for the production and utilization of nuclear energy for industrial purposes;

c) Facilities for the treatment and use of minerals, raw materials, special fissile materials, enriched uranium and radioactive materials;

d) Radioactive waste facilities.

Responsibilities of operators of medical facilities and facilities and activities in Category B are not clearly established in the legislation. These responsibilities depend on the results of the evaluations of the spatial and temporal distribution of the radioactive material dispersed or released from the facilities, as well as on the potential exposures it may cause, and are not consistent with the IAEA GSR Part 7 (see also GS-R-2 para 3.).

Responsibilities are defined in annex 9 point 4.4 bullet d) of Legislative Decree No. 230/1995 for presenting accident scenarios and intervention procedures. However according to GSR Part 7 requirements for establishing arrangements are missing.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team concluded on the basis of information from ISPRA and the ARM that emergency preparedness arrangements are not clearly established in a commensurate manner with the risk.	
(1)	**BASIS: GSR Part 7 Requirement 2 para 4.7 states that** *"The Government shall ensure that all roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly allocated in advance among operating organizations, the regulatory body and response organizations."*
R29	**Recommendation: The Government, in cooperation with the regulatory body, should establish legislation and guidance that clearly define specific requirements on emergency preparedness and response commensurate with the risk in consistency with the IAEA safety standards.**

The IRRS team has been informed that ISPRA´s organizational unit (Nuclear Emergency Coordination Section (NECS) is not involved in the review and assessment process of applications for authorization of facilities.

The IRRS team was informed that the involvement of the section is systematic for some licensing procedures (approval of technical basis for emergency planning, approval of operating rules) and for other cases the involvement is determined by the division management.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Nuclear Emergency Coordination Section (NECS) of ISPRA is not involved in the review and assessment process of applications for authorization of facilities nor in the preparation of authorization conditions. However, NECS is in charge of coordinating the supervision of activities related to the conduct of emergency exercises at facilities site.	
(1)	**BASIS: GSR Part 7 Requirement 2para 4.12 states that** *"The regulatory body is required to establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based [7]. These regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization."*
S15	**Suggestion: ISPRA should consider establishing internal arrangements in order to involve as appropriate NECS in the process of reviewing and assessing applications for authorization.**

Hazard assessment

The operating organizations are responsible for preparing the analysis of the consequences of the postulated accidental events for their facilities. This technical report together with the safety assessment report prepared by ISPRA are provided to the Civil Protection Authorities and constitute the threat (hazard) assessment (technical bases) on which the on-site and off-site emergency plans are prepared. Assessed hazards are not grouped in accordance with the emergency preparedness categories shown in Table 1 of the GSR Part 7 (Table 1 of the GS-R-

2) This table constitutes the basis for a graded approach to the application of requirements and for developing justified and optimized EPR arrangements. At present, these EPR categories are not applied.

ISPRA is involved in the hazard assessment of facilities and activities under the scope of its competence. However, the hazards assessment taking into consideration the results of threat assessments made for nuclear security purposes is in the scope of ISPRA and it will be regulated by a Ministerial Decree already drafted by ISPRA which is waiting for enactment by competent Ministries.

Hazard assessment carried out by ISPRA encompasses non-radiological threats (such as the release of uranium hexafluoride (UF6) or other hazardous chemicals) to people on and off the site that are associated with the practice by taking care of associated interfaces case by case. ISPRA does not carry out the hazard assessment for locations at which there is a significant probability of encountering a dangerous source that has been lost, abandoned, illicitly removed or illicitly transported.

In the National Plan the re-entry of a nuclear-powered satellite or severe nuclear accidents occurring more than 200 km away from the Italian border have not been considered.

In case of facilities under decommissioning the IRRS team was informed that for each stage of the decommissioning process the hazard assessment for planning purposes shall be reviewed.

Based on the interviews, it was noted by the IRRS team, that the Emergency Preparedness Categories as stated in the GSR Part 7 (and previously in the GS-R-2 para 3.6) are not used to provide technical advice based on a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Hazards assessed by ISPRA in order to provide Civil Protection Authorities with the technical basis for planning are not grouped in accordance with the emergency preparedness categories shown in Table 1of the IAEA GSR Part 7.	
(1)	**BASIS: GSR Part 7 Requirement 4 para 4.18 states that** *"These arrangements (for EPR) shall be commensurate with the hazards identified and the potential consequences of an emergency."*
(2)	**BASIS: GSR Part 7 Requirement 4 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."*
S16	**Suggestion: The regulatory body should consider using the internationally recommended Emergency Preparedness Categories (EPC) in order to provide a consistent advice to Civil Protection Authorities, applying a graded approach.**

Protection strategy for a nuclear or radiological emergency

The current regulation establishes the principles of justification and optimization of the intervention shall be applied (art. 115-bis of Legislative Decree No. 230/1995). To this aim the Annex XII of the Legislative Decree No. 230/1995 provides for optimized intervention criteria. A specific requirement to ensure that protection strategies are developed, justified and optimized at the preparedness stage will be established. Moreover, when ISPRA prepares technical basis for EPR planning, considerations are given related to the protective actions that are appropriate to take. ISPRA has been in charge of preparing technical basis for off-site emergency plans of nuclear facilities, for the National Plan of the Protective Actions Against the Radiological Emergencies, for the emergency plan for transport of spent fuel, the emergency plan for transport of radioactive and fissile material and the off-site emergency plan for nuclear powered vessels temporary aground in Italian harbours. Other potential emergency exposure situations are out of the scope of ISPRA.

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Managing operations in an emergency response

An emergency management system is in place in Italy in a consistently manner at local and national level. The implementation of this system makes use of the so called "AUGUSTUS Methodology for Planning and Response" of the Civil Protection Department in which provisions for planning and managing operations for an emergency are included. This is not a mandatory guidance but experiences have demonstrated its usefulness and practicality and it is actually used by all organizations with responsibilities in preparedness and response.

Identifying and notifying a nuclear or radiological emergency and activating an emergency response

The emergency classification, as implemented in the nuclear and radiological emergency plans in Italy, is not consistent with the emergency classification of the IAEA EPR requirements (see also the previous standard GS-R-2 para 4.19). In general, the emergency plans at local (on- and off-site) and at national level make use of two levels of emergency classes: a) Warning level, b) Alarm level.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The requirements related with the emergency classification system are not consistent with the IAEA safety standards.	
(1)	**BASIS: GSR Part 7 Requirement 7 para 5.14 states that** *"The operating organization of a facility or activity…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…. This shall include a system for classifying all types of nuclear or radiological emergency as follows: … Facility emergency… Alert, … Other nuclear or radiological emergency"*
R30	**Recommendation: The Government should ensure that an emergency classification system is established that accounts for the requirements of**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	IAEA safety standards.

Taking mitigation actions

Provisions are included in the regulatory requirements for operating organizations and other response organizations to take mitigation actions in case of a nuclear or radiological emergency.

Requirements for having provisions to take mitigation actions on site at licensed facilities are requested by the provisions in the license concerning the Operating Rules and the Operational Manual, where dedicated sections for facing emergency situation have to be provided. Off-site emergency services are available and capable for supporting the on-site emergency response at facilities and activities in category III. There are provisions according to emergency plans of local authorities for response to radiological emergencies in an unforeseen location including promptly advice or training of first responders. Dedicated emergency plans have been approved for transport of spent fuel, for emergencies in port areas affected by the presence of nuclear powered ships and for the transport of radioactive and fissile materials following the regulatory requirements.

Taking urgent protective actions and other response actions

There are no specific regulatory requirements to promptly assess emergency conditions at facilities and activities based on operational criteria (for example emergency action levels for facilities or observable indicators for emergencies in an unforeseen location) and to take urgent protective actions and other response actions effectively. Criteria to promptly assess the emergency conditions which allow to take urgent protective actions are established within the emergency plans.

Providing instructions, warnings and relevant information to the public for emergency preparedness and response

There are specific regulatory requirements for providing prior information to the public. Responsibilities relay on the Civil Protection Department for the national plan, on the Prefecture for local plans and on the licensee for on-site emergency plan.

Protecting emergency workers and helpers in an emergency

There are requirements for protecting emergency workers. No specific requirements have been established for helpers. Guidance values for restricting the exposure of emergency workers are more restrictive that those stated in the GSR Part 7.

Managing the medical response in a nuclear or radiological emergency

There are some requirements for undertaking an exceptional medical surveillance of workers being affected by a contamination. At the same time, there are not specific regulatory requirements for medical response in a nuclear or radiological emergency. Nevertheless, medical response provided to people affected by the emergency shall be assured by health services whose duties and tasks shall be performed under their institutional responsibilities.

Communicating with the public throughout a nuclear or radiological emergency

There are specific requirements in place for providing information to the public during the event. Responsibilities are allocated to the Prefecture at local level and the Department of Civil Protection at national level.

Taking early protective actions and other response actions

Emergency intervention levels are established by Decree of the President of the Council of Ministers, following the proposal of the Minister of Health, in consultation with the Ministers of Environment, of Interior and for the coordination of civil protection, following the advice of the ISPRA, the National Institute of Health (ISS), the Higher Institute for Work Safety (ISPESL) and the National Research Council (CNR). Operational intervention levels for air, water and soil, as well as for foodstuffs and beverages, both for human and animal use have not been established impairing an effective response as stated in the national plan (a similar requirement was also addressed in GS-R-2 para 4.89).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Operational intervention levels for air, water and soil as well as for foodstuffs and beverages, both for human and animal use, have not been adopted.	
(1)	**BASIS: GSR Part 7 Requirement 14 para 5.81 states that** *"For a transnational emergency in category IV, arrangements shall be made for taking early protective actions and other response actions as appropriate for areas beyond category V, including promptly conducting monitoring and assessment of contamination (a) of food, milk and drinking water and, as appropriate, of commodities other than food, and (b) of vehicles and cargoes that are likely to have contamination, with the aim of mitigating the consequences of a nuclear or radiological emergency and reassurance of the public. These arrangements shall include the use of pre-established operational criteria in accordance with the protection strategy (see para 4.28(4)).''*
R31	**Recommendation: The Government should ensure that operational criteria, including operational interventional levels, are established as appropriate, in order to effectively take early protective actions and other response actions in case of a nuclear or radiological emergency.**

The draft Action Plan provided for the IRRS team by ISPRA foresees preparation of two Decrees in connection with the recommendation above. The first one, to establish the operational intervention levels for air, water and soil and the second to provide the operational intervention levels for foodstuffs and beverages, both for human and animal use.

Managing radioactive waste in an emergency

Specific requirements for managing radioactive waste in a nuclear or radiological emergency are not in place.

Mitigating non-radiological consequences of a nuclear or radiological emergency and of an emergency response

General requirements for rendering psychological and economical support to people involved in an emergency are established by Civil Protection Authorities. Health services under the regional authorities have responsibilities to provide this support on a temporal basis. There are no specific requirements for managing non-radiological consequences in case of a nuclear or radiological emergency.

Requesting, providing and receiving international assistance for emergency preparedness and response

In the framework of the Early Notification Convention of a Nuclear Accident, the Department of Civil Protection is the Competent Authority for domestic and abroad emergencies, and ISPRA is the National Warning Point and the National Competent Authority for Domestic events. The Department of Civil Protection is the Competent Authority Abroad for the Convention on Assistance in Case of a Nuclear Accident or a Radiological Emergency. There are general provisions for requesting, providing and receiving international assistance. Also, there are in place European mechanisms (the Emergency Operation Centre for EU countries) that apply for different emergency situations. Italy has no capabilities registered to RANET.

Terminating a nuclear or radiological emergency

The termination of an emergency is a responsibility of the Head of Department of Civil Protection at national level and the Prefect at local level. There are not specific requirements and criteria for terminating a nuclear or radiological emergency.

It has been identified in the draft Action Plan that there is need for establishing legislative provisions dealing with arrangements for the transition from an emergency exposure situation to an existing or planned exposure situation.

Analysing the nuclear or radiological emergency and the emergency response

There are not specific requirements and criteria for analysing the nuclear or radiological emergency and the emergency response.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Authorities for emergency preparedness and response

The legal framework for emergency preparedness and response in Italy clearly establishes authorities responsible for emergency preparedness and response.

Organization and staffing for emergency preparedness and response

Emergency plans establish the organizational relationships and interfaces between all response organizations during response phase.

In particular, emergency plans establish also organization and provisions for staffing positions within each response organization. As far as the operating organization is concerned, the operating rules, which are approved by ISPRA, establish the staffing positions responsible of the emergency response duties and tasks which shall be taken into consideration by the on-site and off-site emergency plans.

Coordination of emergency preparedness and response

There are in place requirements for the coordination of preparedness activities between the operating organization and authorities at the local, regional and national levels.

Emergency plans establish arrangements for the coordination of the response for a nuclear or radiological emergency between the operating organization and authorities at the local, regional and national levels, and, where appropriate, at the international level.

Plans and procedures for emergency response

Requirements for preparing emergency plans are established in the Legislative Decree No. 230/1995. There are no specific requirements on the content and provisions to prepare

emergency plans. However, AUGUSTUS methodology provides good guidance for preparing emergency plans and its usefulness is greatly accepted.

Logistical support and facilities for emergency response

Provisions for ensuring that adequate logistical support and facilities are provided to enable emergency response functions to be performed effectively in a nuclear or radiological emergency are established also in emergency plans. There are no specific requirements on this topic in the regulations.

Training, drills and exercises for emergency preparedness and response

There are general requirements in the Legislative Decree No. 230/1995. Specific requirements related to the frequency of exercises and the preparation of a training program are included in the conditions of the authorizations for which ISPRA provides technical specifications.

Quality management programme for emergency preparedness and response

Technical specifications attached to the license or authorization requires the operating organizations to establish and implement quality management program (Technical Guides No. 8 and 9) which should cover all types of operations that can make an impact on the emergency response.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

During emergency response ISPRA as a response organization is in charge of providing technical advice to Civil Protection Authorities.

The specific responsibilities are as follow:

a) For the national emergency plan ISPRA is the notification point and in charge of the response initiation. ISPRA is responsible for managing the on-call service for radiation emergencies composed by experts from different areas (emergency coordination, nuclear installations, radiation protection, emergencies during transport, emergencies with dangerous radioactive sources, decision support system, international notification systems, environmental monitoring). This service is available 24/7 days;

b) ISPRA is the National Warning Point and National Competent Authority for domestic emergencies under the Early Notification Convention and has appropriate capabilities to fulfil this function;

c) For off-site emergency plans, ISPRA is in charge of providing advice on radiological assessment and facility´s conditions;

d) ISPRA is the hosting and coordinating organization of the Committee for Data Analysis and Radiological Assessment (CEVaD) giving technical support to this Committee.

To fulfil its tasks, ISPRA owns the Nuclear Emergency Centre and as well sends liaison officers to the local off-site emergency centres as necessary.

Authorities and responsibilities of ISPRA are established in the legislation, there is an internal plan in place, also facilities and logistic support are available and ISPRA participates in emergency exercises. At the same time, procedure for training schedule have not been formally established (similar requirement in GS-R-2 para 5.31).

Technical advice of dose assessments based on the results of monitoring is provided based on expert judgement. “Handbook for the dose evaluation and the environmental monitoring in case

of nuclear and radiological emergencies" adopted by CEVaD Committee in the 2010.*(publication ISPRA series Manual & Guideline - MLG 57/2010* is used as a reference.

The IRRS team was informed that additional technical tools will be developed/implemented for the processing of large amount of georeferenced radiological data (for instance, for processing data coming from national and abroad monitoring networks).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Staff from ISPRA and other governmental authorities participate in international exercises and training activities which are carried out to prepare specialists that will staff the Nuclear Emergency Centre, however there is not a formal training schedule of the personnel or procedures for personnel selection, approved by the management. The participation at the Nuclear Emergency Centre activities are based on the competences of the different units.	
(1)	**BASIS: GSR Part 7 Requirement 25 para 6.28 states that** *"The arrangements (for selection and training the staff) shall include arrangements for continuing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities in an emergency response undergo the specified training."*
R32	**Recommendation: The regulatory body should develop and implement procedures for the selection of personnel and for training to ensure that the personnel selected have the requisite knowledge, skills and abilities to perform their assigned response functions.**

10.5. SUMMARY

Italy has a sound emergency management system in place whose coordination responsibilities are clearly assigned. Arrangements for preparedness and response to a nuclear or radiological emergency are fully integrated into the system with responsibilities and authorities well allocated to response organizations, the government and governmental agencies.

Functional requirements and requirements for infrastructure are in place. In some cases, these requirements are established in the framework of general emergency preparedness and response requirements of the Department of Civil Protection. Some general requirements need specifications for nuclear and radiological emergencies. It is expected that requirements of the GSR Part 7 be considered for improvements to be implemented by the emergency management system.

11. ADDITIONAL AREAS

11.1. OCCUPATIONAL RADIATION PROTECTION

Legal and regulatory framework

Legislative Decree 17 March 1995 No. 230 as amended and in particular Chapter VIII and Annexes IV - VI and IX, establishes the provisions for occupational health and safety in workplaces where ionizing radiation is involved. The decree has in anticipation transposed parts of the EU Council Directive 96/29 EURATOM. At present, requirements of Council Directive 2013/59 EURATOM are about to be transposed. Several technical documents supplement the legal framework.

The regulations of Legislative Decree No. 230/1995 and Legislative Decree No. 81/2008, which is the current regulatory framework on occupational health and safety for all workplaces, cover the requirements of GSR Part 3 for occupational radiation protection to a wide extent, albeit not completely. Some requirements concerning the protection of workers are more restrictive than required in GSR Part 3.

The few discrepancies between the GSR Part 3 requirements and the Italian legislation refer mainly to requirements that are also demanded in the EC Directive 2013/59 EURATOM and are subject to planned implementation. Some other requirements cannot be juridically formulated in a legally binding manner - these concern management tasks and the cooperation and communication between employer, registrant, licensee and worker.

The legal and administrative competencies in the field of occupational radiation protection are both centrally and regionally shared between State Ministries and various governmental institutions of 20 political regions. This inhomogeneous field of competencies leads to the fact that essential information and data about individual exposure, dosimetric services, and also radioactive sources are fragmented across the country and not available within a countrywide information system for radiation protection.

Responsibilities of the qualified expert, registrant, licensees and employers

In the Italian regulatory framework for occupational radiation protection, the qualified expert (QE) plays a central role between registrant, licensee, employer and regulatory body. The QE has to cover the full range of requirements in occupational radiation protection and, for example, has official responsibilities for workplace classifications and classification of workers, technical and administrative protection measures, written instructions and local rules, organization of individual monitoring, assessment of official doses, dose limit control, and the cooperation between licensee, worker and regulatory body. However, the position of the QE could be improved by a better availability of data about individual dose history and the availability of legally-approved services for individual monitoring.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The requirements for the qualification and technical skills of a qualified expert are challenging and ambitious. There exist three qualification levels with high formal requirements (university degree, technical schools, etc.). This sophisticated standard creates a high reputation of the qualified expert and thus supports their credibility and authority.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Requirement 2 para 2.21 states that** *"The government shall ensure that requirements are established for:* *(a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;* *(b) The formal recognition of qualified experts"*
GP3	**Good Practice: The Italian system of education and training for qualified experts is of outstanding high quality and is exemplary in radiation protection.**

The legal requirements of employer, registrant and licensee for occupational radiation protection are generally in line with GSR Part 3 and are under the observation and control of the QE. The optimization principle is applied, albeit without use of dose constraints. It is under development in the transposition process of EC Directive 2013/59/Euratom.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The application of the optimization principle is legally acknowledged and part of the duties of the licensee, worker and qualified expert. The concept of dose constraints in optimization is generally not applied.	
(1)	**BASIS: GSR Part 3 Requirement 11, para 3.22 (c) states that** *"The Government or the regulatory body shall establish or approve dose constraints on dose and on risk, as appropriate, or shall establish or approve a process for establishing such constraints, to be used in the optimization of protection and safety"*
R33	**Recommendation: The Government and the regulatory body should establish a process to introduce the use of dose constraints in the optimization for protection and safety of workers.**

It can generally be stated that the absence of explicitly formulated articles in the legislative decrees does not at all mean that a certain requirement is not followed. These tasks are usually embedded in the duties of the QE.

Services for individual monitoring

The exact number of Services for individual monitoring in Italy is unknown but is estimated to be around 70. When a new dosimetry service (DS) appears on the market, it notifies ISPRA of its existence, but further information (including the closure of a DS) is not necessarily reported. There is no official approval required to establish DS. Accreditation or quality management programs for the Service or the participation in inter-comparison measurements are legally not required. The responsibility for verifying the effectiveness of dosimeters and their periodic calibration falls on the shoulders of the QE (Art. 79 LD 230/95). The QE chooses a DS based on his personal knowledge about the quality of the DS and the costs. The lack of legally-binding requirements for a uniform quality standard for DS is:

- a disadvantage for the quality of dose monitoring;

- a burden for the QE as it weakens his credibility in assessing official doses and, thus, his reputation and authority as a qualified expert.

Legislative Decrees for the calibration of measurement equipment (Ministry of Health) and for Service approval (Ministry of Labour) are presently under preparation. This issue is addressed in Recommendation R6 in Module 1.

Dose recording

Information about individual doses of workers are recorded and kept by the QE. The record data fields are well-defined and complete for the monitoring requirements. The correct assignment of dose records to an individual worker is provided by the use of the worker's tax number as a unique identification number. The QE usually receives and keeps also dose information about former exposures that a worker has received at workplaces of previous employers, provided of course that they were recorded by other QEs. An electronic information system to register and retrieve individual dose histories does not exist.

Legislative Decree No. 230/1995 requests a national dose registry, but this has not yet been put into practice. By having no national dose register, Italy cannot:

(1) provide complete dose histories for radiation workers;

(2) produce statistical analyses of doses and their changes over the time for different occupational work sectors, activities and other aspects.

As a consequence, Italy has neither a complete nor reliable overview of the number of occupationally exposed workers and their doses. Reports with annual national dose statistics and trends in different work sectors and occupational fields do not exist. The general effectiveness of optimization in the various occupational fields can, thus, not be quantified statistically. Italy is also not able to participate in international activities such as UNSCEAR surveys on occupational radiation exposure.

Site visit /Gemelli Hospital

The site visit in the Gemelli hospital showed that occupational radiation protection is very well organized within the hospital due to a high commitment of the QE.

11.2. Control of RADIOACTIVE discharges, MATERIALS FOR clearance, AND EXISTING EXPOSURES SITUATIONS; environmental monitoring FOR PUBLIC RADIATION PROTECTION

Control of discharges

According to Italian regulations, before authorization a facility must comply with the fundamental principles of safety and radiation protection (justification, optimization, dose limits for workers and public exposure). Authorized limits for discharges are based on a criterion of an effective dose not exceeding 10 µSv/year for the members of the public. This is established in a so called "discharge formula". The application of this formula is evaluated in terms of consistency of input data with operating conditions, the type and concentration of nuclides, assessment methodology etc.

According to the national system, assessment of doses is done by a QE on the behalf of the registrant/licensee. Results of environmental monitoring and data on discharges as well as assessments of doses to the public are reported by the licensee to the regulatory body annually. Regulatory bodies (regional and national) make intensive independent measurements of discharges.

Exemption and Clearance

Practices to be exempted from requirements have been determined. A general criteria in Italy for unrestricted releases from any installation is made by using numerical values given in Legistative Decree No.230/1995 (Art.154, para 2). Radioactive materials from practices can be unconditionally released from regulatory control if the radionuclides concerned comply with conditions regarding both activity concentration and radioactive half-life:

− Activity concentration ≤ 1 Bq/g, and

− Half-life < 75 days

These conditions are consistent with the criteria given in GSR Part 3.

No general clearance values are used for nuclides with half-lives >75 days, but values are specified on a case-by-case basis fulfilling the criteria given in GSR Part 3, Schedule I. A specific Technical Guidance for clearance is under development in ISPRA.

Specific exemption to the prohibitions for putting into market, produce, import or use products or goods with added radioactivity, are granted by the Minister of Health. This is possible according to the IAEA requirements but will be forbidden, when the State has implemented the new EC BSS.

Monitoring and reporting

The Italian law establishes the responsibilities of the regulatory body and of relevant parties to ensure that programmes for source monitoring, environmental radioactivity monitoring and radiological surveillance of foodstuffs are in place.

Environmental monitoring is organized in three different levels:

- local site level (responsibility of licencee);
- regional level (21 regional networks, responsibility of provincial environmental agencies);
- national level (3 networks, coordinated by ISPRA).

Responsibilities at the national level are shared by two Ministries. ISPRA carries out reviews for approval and revision of programmes. Both regional agencies and ISPRA make provisions for independent monitoring.

For improving quality and training nationally, they have produced a comprehensive Handbook (Manuale), which is available on the internet, and which covers all monitoring methods including sampling, and Guidelines for Monitoring (Linee Guida) consisting of a strategy for monitoring as well as information on equipment and the personnel needed. The Handbook is updated frequently.

ISPRA, in cooperation with National Institute for Health, is responsible for assessment of public exposure. The operator's monitoring programmes for nuclear installations and other practices are approved by ISPRA. Licencees submit annual reports to ISPRA on the results of monitoring, discharges and dose rate assessments, but a total public exposure assessment has not been made based on all the results collated. No strategy or formula for publishing results exists.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The regulatory bodies (regional and national) are making independent monitoring, but the total public exposure assessment in the State has not been performed. Some regulatory bodies publish results from source monitoring and environmental

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
monitoring programmes and assessments of doses to public, but used practises are incomplete.	
(1)	**BASIS: GSR Part 3, para 3.135 (d) states, that** *"The regulatory body shall be responsible for assessment of the total public exposure due to authorized sources and practises in the State on the basis of monitoring data provided by registrants and licencees and with the use of data from independent monitoring and assessments."*
(2)	**BASIS: GSR Part 3, Requirement 32 para 3.136 states *that "***the regulatory shall publish or shall make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure."
R34	**Recommendation: The regulatory body should assess the total public exposure due to authorized sources and practises in the State.**
S17	**Suggestion: The regulatory body should consider publishing at national level results from source monitoring and environmental monitoring programmes and dose assessments.**

Existing exposure situations

Existing exposure situations across the country have been identified that are of concern from the point of view of radiation protection, and a comprehensive list of different kinds of NORM sites has been developed. However, no reference levels have been established for existing exposure situations.

The legal framework identifies the situation that are included in its scope, sets objectives and principles for remediation, taking account both chemical and radiological contamination, measures and responsibilities. Generally persons or organizations responsible for areas with residual radioactive material are identified from the site history. The persons or organization responsible for the areas are responsible for planning, implementing and verifying the results of remedial actions. Prefects (as a regulatory body) define safety criteria and undertake review of remediation plans on a site-specific basis. However, a national system of records for such sites and remedial activities do not exist.

A national survey of radon in dwellings was carried out 1997. A more detailed survey of radon has been carried out subsequently in the region of Lazio and the results are available on web pages. ISPRA, together with regional authorities, has also produced guidance for citizens on radon-safe buildings and on remediation. The government has previously established an action plan to control public exposure due to radon indoors when the radon levels are of concern for public health. The plan is not evaluated and does not fulfill all the requirements given in GSR Part 3.

Reference levels for radionuclides in drinking water have been established, but not for all commodities such as construction materials, food and livestock feed. However specific requirements will be introduced into Italian legislation during implementation of the new EC BSS and this is also identified in ISPRA's Action Plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Government has identified a comprehensive list of specifications of existing exposure situations, and actions levels for the public are established. However reference levels are not established.	
(1)	**BASIS: GSR Part 3 Requirement 47, para 5.2 states that** *"The Government shall ensure that, when an existing exposure situation is identified, responsibilities for protection and safety are assigned and appropriate reference levels are established."*
(2)	**BASIS: GSR Part 3 Requirement 47, para 5.4 states that** *"The regulatory body or other relevant authority assigned to establish a protection strategy for an existing exposure situation shall ensure that it specifies:* *(a) The objectives to be achieved by means of the protection strategy;* *(b) Appropriate reference levels."*
(3)	**BASIS: GSR Part 3 Requirement 47, para 5.9 states that** *"The regulatory body or other relevant authority shall periodically review the reference levels to ensure that they remain appropriate in the light of the prevailing circumstances."*
R35	**Recommendation: The Government should ensure that appropriate reference levels are established and that a protection strategy for existing exposure situations is established and implemented. The regulatory body should periodically review the appropriateness of the reference levels.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The overall protection strategies, including the waste management, are within the exclusive jurisdiction of the State (prefectures -territorial offices of Government or civil protection, depending on the extent and urgency of the intervention).Though all information are recorded by prefectures and persons responsible for the remedial actions, a national system for maintaining, retrieval and amendment of records, that cover the nature and the extent of contamination, the decision made before, during and after remediation, and information on verification of the results of remedial actions including the results of monitoring programmes, does not exist.	
(1)	**BASIS: GSR Part 3, Requirement 49, para 5.10 (d) states, that** *"the Government shall ensure that provision is made in the framework for protection and safety for ….An appropriate system for maintaining retrieval and amendment of records that cover the nature and the extent of contamination; the decisions made before, during and after remediation, and information on verification of the results of remediation actions, including the results of all monitoring programmes after completion of the remedial actions."*
R36	**Recommendation: The Government should ensure that a provision is made**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	in the framework for protection and safety for an appropriate national system of records covering all the data gathered before, during and after remediation, in line with IAEA safety standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Relevant information regarding exposure due to radon is provided by the regulatory body. Only in some areas of the State a comprehensive radon mapping from activity concentrations of radon in dwellings has been made and published. The existing action plan is not appropriated to ensure efficient reduction of activity concentration in buildings and doesn't fulfil the IAEA requirements.	
(1)	**BASIS: GSR Part 3 Requirement 50 states that** "*The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors."*
(2)	**BASIS: GSR Part 3 Requirement 50 para 5.19 states that** *"As part of its responsibilities, as required in para 5.3, the government shall ensure that:* *(a) Information is gathered on activity concentrations of radon in dwellings and other buildings with high occupancy factors for members of the public through appropriate means, such as representative radon surveys;* *(b) Relevant information on exposure due to radon and the associated health risks, including the increased risks relating to smoking, is provided to the public and other interested parties."*
(3)	**BASIS: GSR Part 3 Requirement 50 para 5.20 states that** "*Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered as required in para 5.19(a), the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings, which includes:* *(a) Establishing an appropriate reference level for 222Rn for dwellings and other buildings with high occupancy factors for members of the public, with account taken of the prevailing social and economic circumstances, that in general will not exceed an annual average activity concentration due to 222Rn of 300 Bq/m3;* *(b) Reducing activity concentrations of 222Rn and consequent exposures to levels at which protection is optimized;* *(c) Giving priority to actions to reduce activity concentrations of 222Rn in those situations for which such action is likely to be most effective;* *(d) Including in building codes appropriate preventive measures and corrective actions to prevent the ingress of 222Rn and to facilitate further actions wherever necessary."*
(4)	**BASIS: GSR Part 3 Requirement 50 para 5.21states that** *"The government shall assign responsibility for:* *(a) Establishing and implementing the action plan for controlling public*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	exposure due to 222Rn indoors; *(b) Determining the circumstances under which actions are to be mandatory or are to be voluntary, with account taken of legal requirements and of the prevailing social and economic circumstances."*
R37	**Recommendation: The Government should extend the mapping of activity concentrations of radon in dwellings and should review, establish and implement the action plan for controlling public exposure due to radon indoors.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Government has implemented specific reference levels for drinking water. However, no reference levels have been established for other commodities such as construction materials, food and feed.	
(1)	**BASIS: GSR Part 3, Requirement 51 para 5.22 states that** *"The regulatory body or other relevant authority shall establish specific reference levels for exposure due to radionuclides in commodities such as construction materials, food and feed, and in drinking water, each of which shall typically be expressed as, or be based on, an annual effective dose to the representative person that generally does not exceed a value of about 1 mSv."*
R38	**Recommendation: The regulatory body should establish specific reference levels for exposure due to radionuclides in commodities.**

11.3. SUMMARY

As a result of the central position and high qualification of the QE, occupational radiation protection in Italy at the individual level is good and effective, so that individual workers are well protected. Structural deficits like the omission of the approval of Services for individual monitoring and the lack of a national dose register hamper the daily work of the QE and the provision of proof of the effectiveness of optimization in the Italian system for occupational radiation protection. The education and training system for qualified experts is outstanding and exemplary.

The IRRS team considers that ISPRA meets the IAEA requirements with respect to control of discharges, exemption and clearance. The IRRS team made recommendations aimed at improving management at the national level of environmental monitoring, dose assessments and recording of remediation actions. The IRRS team also recommended that the Government establishes reference levels for existing exposure situations and implements a new radon action plan for reducing indoor radon. At the same time, the IRRS team observed that ISPRA has documented an Action Plan, to improve compliance with the requirements of GSR Part 3 including NORM waste management, strategy for remediation situations, coordination in remediation activities, reference levels for radon in dwellings and public buildings, and developing a data base for indoor radon.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

Italy ratified the Convention on Physical Protection of Nuclear Materials (CPPNM) with Act No. 704/1982. CPPNM amendments were signed in 2005 and then ratified with Act No.58/2015.

The Act No. 58/2015 requires that a Decree of the Ministry of Economic Development in agreement with the Ministers of Interior and Environment, Land and Sea Protection on physical protection requirements for nuclear materials and installations is needed to complete the implementation of the provisions of the Act. This ministerial Decree is also of relevance for the interface between nuclear safety and security.

The IRRS team noted that the ministerial Decree is planned to be issued in the middle of 2017 as identified by the Italian counterpart in its draft action plan.

12.2. REGULATORY OVERSIGHT ACTIVITIES

The Act No.58/2015 specifies the involved competent authorities.

The Ministry of Economic Development is responsible for licensing and approval of physical protection plans. The Ministry of Internal Affairs is identified as responsible for prevention of illicit acts against nuclear facilities and activities and the establishment and update of design basis threats. ISPRA supports the above ministries in the licensing, maintenance and review of physical protection plans and performs inspections to verify compliance, jointly with the Ministry of Internal Affairs, as appropriate. The IRRS team was informed about oversight and control activities, including in the transport and emergency preparedness area and no findings were identified.

12.3. INTERFACE AMONG AUTHORITIES

The IRRS team was informed on how it is ascertained that implemented safety and security measures do not compromise the others and vice-versa. In this sense, the regulatory body ISPRA was central as having responsibilities in both areas. The IRRS team was briefed by ISPRA and representatives of the Ministry of Internal Affairs on authorization and assessment of facilities and activities, optimization of safety with aspects bearing on security and control of nuclear material and specifically some more integrated activities in the areas of transport of nuclear material.

The IRRS team acknowledged the coordination in the planning of transports of nuclear material and the corresponding measures to apply an integrated approach to safety and security in implementation and the use of feed-back experience and recognized that the implemented activities, including the applied measures and tools were integrated in a fashion that is worthy of notice.

12.4. SUMMARY

The IRRS team reviewed the interfaces of safety with nuclear security and concluded that these activities were carried out in compliance with the IAEA requirements and identified commendable activities.

APPENDIX 1 POLICY ISSUES

The following topics were addressed with the counterpart during the policy issues discussion on the afternoon of 25 November 2016:

1. Transparency of the regulatory body and relations with stakeholders
2. Siting process of disposal facilities and participation of the public.

The objectives of the policy issues discussion were to share experiences and views among IRRS team members and their Italian counterparts. The discussion was attended by all of the IRRS team members and most of the ISPRA staff along with representatives of the Ministry of Economic Development and the Ministry of the Environment.

1. Transparency of the regulatory body and relations with stakeholders

An ISPRA senior manager opened the meeting by noting that the regulatory body is at the centre of a complex system of relations and liaisons. Key subjects involved are the Public, the Authorized Parties, other Administrations, the Government and the Parliament. He emphasized that the regulatory body is accountable for the effectiveness of its regulatory function and it has therefore to be transparent on its decision making process. It has also to ensure that information on the safety of nuclear installations and activities and on related radiation protection issues are properly conveyed to interested parties. He also noted that different tools are available to support the process of the regulatory body to be transparent and informative in its processes. These tools include public hearings, use of the website, press release etc. The choice of the general or detailed regulatory documentation to be disclosed is an important issue to be addressed and leads to the question - how much transparency is enough?

The deputy team leader started the discussion by mentioned that, in France, there are two important things for the regulator to consider in this regard. The first is that there are higher expectations from the public regarding information about regulatory decisions. The second is that there has been an Increase in legal requirements that allow for the public to have more opportunities to intervene. He also mentioned the Aarhus convention for EU member states that sets out three pillars:

- Right to know
- Right to participate
- Right to justice

Following this, various members of the team related information about the situation in their countries. These are summarized below:

Finland

- Transparency is key
- Changed philosophy to now make everything public that is not confidential (even redact confidential documents)
- Let public decide what is relevant to them
- Should make all documents understandable to public (plain language)

Sweden

- Remember the INSAG document on safety culture – public needs access to information to be able to participate
- Consider optimal amount of information – too much is bad and too little is also bad

- Public should be involved in meetings as appropriate
- Regulator is responsible for informing public about risk of radiation – in plain language
- honesty is always best policy - everything doesn't have to be positive

Cuba

- Consider not best site for nuclear facilities but the best available site – considering public opinion

Luxemburg

- Struggling with how to deal with lower risk situations - refer things to local ministries – but politics often intervene

Switzerland

- There is increasing opposition from NGOs who are asking for all types of documents. As a result, the regulator had to hire 4 people to respond (2 lawyers and 2 communication specialists)
- The possibility that more documents may be made public is having an impact on experts writing their safety reports

USA

- Always be honest with public because it only takes one instance of perceived dishonesty by the regulator to destroy public confidence

The deputy team leader summarized the discussion by stating that the purpose of this effort is to improve the regulatory decision-making process. He noted that the public often has very good questions and that it is important to train staff on how to interact with public.

The deputy team leader pointed out that the involvement of interested parties is not only a new way to communicate but should be viewed as a new way to work in order to improve the quality, visibility and the credibility of the regulatory body functions and duties. In this regard, it is essential to consider this issue in policy making.

2. Siting process of disposal facilities and participation of the public

An ISPRA senior manager opened the discussion by noting that Italy is in the process to site a National Repository of radioactive waste. It will be made of a near surface disposal facility for low and intermediate level waste and a facility for the long term storage of intermediate and high level waste. According to the national legislation the National Repository will be sited following a predefined process based upon the participation and the consensus of interested parties and involved communities. This process envisages the publication by the implementer of a National Chart of potentially suitable areas after the regulatory review of the competent regulatory Authority and the authorization by the competent Ministries. The identification of the potentially suitable areas has to be conducted in compliance with the criteria set up by the competent regulatory authority. Following the publication of the Chart a national seminar is envisaged, where all interested parties are invited to participate and to express their comments and observations. Taking into account the results of the seminar the National Chart will be updated and finally approved.

On the basis of the approved Chart each one of the regions where the identified potentially suitable areas are located will be invited to declare their interest and availability to accept

detailed sites investigations with the view of finally hosting the national Repository. When the investigations will be completed the selected site will be proposed by the implementer and approved by the competent Ministries, based upon the advice of the competent regulatory Authority.

The team leader started this part of the discussion by noting that Sweden is closing in on a process for reviewing and accepting a facility for HLW. He identified a few key points to consider:

- The public expects to be involved in the process
- Strong political support is essential – sends signals
- Need clear separation of roles – operator vs. regulator
- Criteria should be very clear – technical and process
- Early public involvement is important
- Government also decided that financial incentives for regions could be appropriate

Switzerland

- Process of stakeholder involvement is led by ministry of energy for deep geological repository
- Each of 5 regions hold public conferences at least twice per year (started in 90s)
    - Led by ministry of energy and attended by regulator, NGOs, politicians, press, etc.
    - Now down to 2 regions
- Technical forum on safety also held twice per year at ENSI – public meeting that allows for pre-submitted questions

UK

- Regulator informs public of process and technical guidance
- Waste facilities are different than NPPs because they will remain with communities for many years – public involvement is essential
- First started looking at geology but was only technical and didn't involve public – failed and public is sceptical as a result
- Next asked for volunteers but that didn't work
- Current process is combination of both (geological screening and volunteers)
- 20 year process envisaged to allow for building public trust

Hungary

- Surface type repository built in 70s (for institutional waste)
- Second will be a near-surface in rock (for low and intermediate waste)
- Considered an old uranium mine for HLW but it flooded and was found not suitable
- Currently doing research for new site
- Incentives – government provides funds to inform public and puts restrictions on the use of these funds
- Regulator is now responsible for potential repository (used to be minister of health)
    - Issued regulations for safety of repository but are still working on siting criteria
    - Public interest has been mainly related to environmental impacts
    - New requirement for public hearing on any change in license

France

- Waiting for application from operator for deep geological disposal
- The related process started in 1991
    - Expectation from public of Increased participation
    - New requirements
- National policy
    - Reduce volume of waste
    - Is deep repository possible?
    - How to keep waste safe
- 2006 - began to develop combined waste management plan - technical document
    - Technical WG
    - Document will be made public
- Next step is national debate on waste management plan
- Regulatory body issued guidance on site selection – includes criteria for safety

Finland

- Started in 1983 with government decision – public involvement critical
- Started with 100 possible sites
- 1992 – selected 5 sites but some were vetoed by municipalities – all had environmental reviews completed
- 2000 – selected site near NPPs
- Process led by ministry of economic development – STUK participated as technical role
- Made regulation for deep geological repository
- 2015 was approved by STUK and government authorized
- Public opinion has gradually increased over the past 20 years – now 60% believes it is safe to store HLW in Finnish geological repository

At the conclusion of the discussion, the team leader noted that everyone should take advantage of the fact that the IRRS team will be here for another week. He encouraged the Italian participants to seek out team members to ask them more questions.

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Ingemar Lund	**L.Matteocci, G.Sedda**

APPENDIX IV MISSION PROGRAMME

IRRS MISSION PROGRAMME		
Sunday 20 November 2016		
IRRS Initial Review Team Meeting		**Venue and Participants**
13:30–17:30	Opening remarks by the IRRS team Leader Introduction by IAEA Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (TL, IAEA) First impression from experts arising from the Advanced Reference Material (ARM) (All Experts) Administrative arrangements (ISPRA) and IRRS Liaison Officer, IAEA): Detailed Mission Programme	Meeting Room in Hotel Ripa Roma Participants: the IRRS team + the LOs Module Leaders to prepare slides for the TL presentation for the Entrance Meeting.
Monday 21 November 2016		
IRRS Entrance Meeting		
09:00–12.00	09:00 Arrival 09:30 ISPRA DG – Welcoming Address 09:45 IRRS Coordinator – The IRRS programme 10:00 IRRS Team Leader – Expectations for the Mission and introduction of the IRRS team 10:30 Coffee break and Group Photo 11:00 ISPRA – Regulatory Overview, self- assessment results (strength, challenges, action plan) 11:45 Questions?	ISPRA *Building B Conference Room 7th* Floor ISPRA Conference Room Building A Participants: ISPRA Management and staff, Officials from relevant organizations, the IRRS team + the LOs
12:30–13:30	Lunch	
13:30–17:00	Interviews and Discussions with Counterparts (parallel discussions)	Topics, Counterparts and Offices: **M 1,2,3/** *Building B Conference Room 7th floor* **S. Laporta - DG of ISPRA, L.Matteocci,** R.Ranieri, L.Bologna

IRRS MISSION PROGRAMME		
		Common Discussion Topics: Regulation and guides/Authorization Processes – **Sources (M 5-9)**/ *Building A Room 117* – **Waste Facilities and Decommissioning (M 5-9)** / *Building A Room 117* – **Research Reactors (M 5-9)**/ *Building A Room 117* Modules counterparts + representatives from Piedmont Region **M4** *– Building A –Room 419* **N. Cipriani**, De Benedetti, A. Ensoli, **Transport (M 5-9)** - *Building A –Room 412* **S. Trivelloni,** P. Alvano, G. Palmieri, **M10 Emergency**- *Building A –Room 420* **P. Zeppa,**S. Scarpato,S. Zennaro **M11 Occupational exposure control** - *Building A –Room 426* P. Bitonti, L. Tolazzi, **A. Principe,** F.Luciani **M11 – Environmental Monitoring and Control of Discharges** - *Building A – Room 418* **R.Ocone, S.Fontani** G.Menna – Representatives of Regional Environmental Protection Agency of Piedmont Region
17:00–18:00	Daily IRRS Review Team meeting	ISPRA Conference Room 7th floor Building B Participants: the IRRS team + LO.
Tuesday, 22 November 2016		
Daily Discussions / Interviews		
09:00–12:30	Interviews and discussions with counterparts (parallel discussions)	Counterparts and Team Members **M 1,2,3**/*Building B Conference Room 7th floor* **S. Laporta - DG of ISPRA, L.Matteocci,** R.Ranieri, L.Bologna 9:00-10:30 - Representatives from Ministry of Economic Development,

IRRS MISSION PROGRAMME		
		Ministry of Environment, Land and Sea Protection **Common Discussion Topics: Authorization Processes** **Sources (M 5-9)**/ *Building A Room 117* **Waste Facilities and Decommissioning (M 5-9)**/ *Building A Room 117* **Research Reactors (M 5-9)**/ *Building A Room 117* Modules counterparts 11:00 – 12:30 Representatives from Ministry of Economic Development, Ministry of Environment, Land and Sea Protection and Piedmont Region. **M4** *– Building A –Room 419* **N. Cipriani,** De Benedetti, A. Ensoli, **Transport (M 5-9) -** *Building A –Room 412* **S. Trivelloni,** P. Alvano, G. Palmieri **M10 Emergency** - *Building A –Room 420* **P. Zeppa**,S.Scarpato,S.Zennaro **M11 Occupational exposure control** - *Building A –Room 426* P. Bitonti , L. Tolazzi, **A. Principe,** F.Luciani + representatives from Ministry of Labour and Social Affairs **M11 – Environmental Monitoring and Control of Discharges** - *Building A – Room 418* **R.Ocone,** G.Menna, **S.Fontani** – Representatives of Regional Environmental Protection Agency of Piedmont Region
12:30–13:30	Lunch	
13:30–17:00		Counterparts and Team Members: Prefer Counterpart Offices **M 1,2,3/** *Building B Conference Room 7th floor* **S. Laporta - DG of ISPRA, L.Matteocci,** R.Ranieri, L.Bologna **Sources (M 5-9)**/ *Building A Room 417* **J.Wells,** L.Tolazzi, C.Salierno, L.Bologna, S. Principe, S.Venga

IRRS MISSION PROGRAMME		
		Waste Facilities and Decommissioning (M 5,6,9) / *Building A Room 117* **A.Orazi, M.Dionisi,** F.Trenta**,** P.Putortì, N.Cipriani, B.Giannone, A.Santilli, M.Gervasi. **Research Reactors (M 5-9**)/*Building B Room 4th floor* **A.Buccafurni,** F.P.Michetti, De Benedetti **Transport (M 5-9)** - *Building A –Room 412* **S. Trivelloni**, P. Alvano, G. Palmieri, **M10 Emergency**- *Building A –Room 420* **P. Zeppa,** S.Scarpato,S. Zennaro **M11 – Chronic Exposure and remediation** - *Building A –Room 418* **L. Bologna, S.Venga, G. Torri,**
17:00–18:00	Daily IRRS Review Team meeting	ISPRA Conference Room 7th floor Building B Participants: the IRRS team + LO.
Wednesday 23 November 2016		
Daily Discussions / Interviews		
09:00–12:30	Interviews and discussions with counterparts for all modules	Counterparts and Team Members: Prefer Counterpart Offices **M 1,2,3/** *Building B Conference Room 7th floor* **L.Matteocci,** R.Ranieri, L.Bologna Module 12 Rep from Ministry of Interior **Sources (M 5-9**)/ *Building A Room 417* **J.Wells,** L.Tolazzi, L.Bologna, C.Salierno, A.Principe, S.Venga **Waste Facilities and Decommissioning (M 5, 6, 9)** / *Building A Room 117* **A.Orazi, M.Dionisi,** F.Trenta, P.Putortì, N.Cipriani, B.Giannone, A.Santilli, M.Gervasi, **Research Reactors (M 5-9**)/*Building B Room 4th floor* **A.Buccafurni,**F.P.Michetti, G.DeBenedetti **Transport (M 5-9)** - *Building A –Room 412*

IRRS MISSION PROGRAMME		
		S. Trivelloni, P. Alvano, G. Palmieri, **M10 Emergency**- *Building A –Room 420* **P. Zeppa,** S.Scarpato, S.Zennaro **M11 – Chronic Exposure and Remediation** - *Building A –Room 418* **L.Bologna, G. Torri, S.Venga**, F.Salvi **M12 – Interface with security** – *Building A – Room 428* **L.Matteocci, G.Sedda** + representatives of Ministry of Interior
12:30–13:30	Lunch	
14:40–16:00	Visit to State Under Secretary office	TL, DTL, TC, M1-3
13:30–16:00	Interviews and discussions with counterparts for all modules	Counterparts and Team Members **M 1,2,3/***Interviews and discussions Building B Conference Room 7th floor* *+ Visit to State Undersecretary of the Ministry of Environment, Land and Sea Protection* **S. Laporta, L. Matteocci** **Sources (M 5-9**)/ *Building A Room 417* **J.Wells, L.Tolazzi,** L.Bologna, C.Salierno, A.Principe, S.Venga **Waste Facilities and Decommissioning (M 7, 8)** / *Building A Room 117* **F.Michetti,** P.Bitonti, F. Trenta, P. Putortì, **N. Cipriani** **M4** – *Building A –Room 419* **N. Cipriani,** A. Ensoli **Transport (M 5-9)** - *Building A –Room 412* **S. Trivelloni,** P. Alvano, G. Palmieri, **M10 Emergency**- *Building A –Room 420* **P. Zeppa**,S. Scarpato,S. Zennaro **M11 Occupational exposure control**- *Building A –Room 426* P. Bitonti, L. Tolazzi, **A. Principe,** F.Luciano **M11 – Clearance of materials from nuclear installations** - *Building A – Room 418* **M. Altavilla**, A.Orazi
16:00–17:00	Writing first draft of preliminary findings (Rs, Ss and GPs)	Venue : ISPRA *Conference Room 7th floor Building B*
17:00–18:00	Daily IRRS Review Team meeting	ISPRA Conference Room 7th floor

IRRS MISSION PROGRAMME		
		Building B Participants: the IRRS team + LO.
Thursday 24 November 2016		
Daily Discussions / Interviews		
08:00–16:00[1]	Site visits to a Medical Installation (A. Gemelli Hospital)	Participants: Team Members G.Frasch, P.Majerus, C.Letzelter – ISPRA counterparts: J.Wells, L.Tolazzi
	Site visit to TRIGA Research Reactor at Casaccia Center	Participants: Team Members S.Magruder, A.Persic - ISPRA counterparts: A.Buccafurni, A. Orazi,
	Site visit to Nucleco Waste Management Facility at Casaccia Center	Participants: Team Members L.Jova Sed, D.Bennet, ISPRA counterparts: F.P.Michetti M.Dionisi, B.Giannone
07:00–19:00	Site Visit at Garigliano NPP (under decommissioning)	Team Members P.Francois' T.Ikaheimonen, F.Lorand, P.F.Jerez Vegueria - ISPRA Participants: P.Bitonti, F. Trenta, N.Cipriani, M.Gervasi
09:00– 15:00	Interviews and discussions with counterparts if needed (parallel discussions)	Counterparts and Team Members
12:00 – 13:00	Lunch	
09: 00 –	Report Writing	Team Members not participating in site visits Venue : ISPRA *Conference Room 7th floor Building B*
17:00–18:00	Briefing about site visits and Daily IRRS Review Team Meeting: recommendation, suggestions and good practices	ISPRA *Conference Room 7th floor Building B* Participants: the IRRS team + LO.
Friday 25 November 2016		
Daily Discussions/Interview		
09:00–16:00	Follow-up Interviews and discussions with counterparts (parallel discussions) Report writing, Finalize Observations, Recommendations, Suggestions and Good Practices	Counterparts and Offices: **M 1,2,3/** *Building B Conference Room 7th floor* **Sources (M 5-9)**/ *Building A Room 417* **Waste Facilities and Decommissioning (M 5-9)**/*Building A Room 117* **Research Reactors (M 5-9)**/*Building B Room 4th floor*

[1] More time may be given if needed for all site visits.

IRRS MISSION PROGRAMME		
		M4 – *Building A –Room 419* **Transport (M 5-9)** - *Building A –Room 412* **M10 Emergency**- *Building A –Room 420* **M11 Occupational exposure control**- *Building A –Room 426* **M11 – Chronic Exposure and remediation** - *Building A – Room 418* **M12 – Interface with security** – *Building A – Room 428*
12:30–13:30	Lunch	
13:30–16:00[2]	Policy issue discussion:	TL, TC and Reviewers Venue : ISPRA *Building A Room 117*
16:00–18:00	Daily IRRS Review Team Meeting	ISPRA Conference Room 7th floor Building B Participants: the IRRS team + LO.
Saturday 26 November 2016		
Daily Discussions		
Team members write draft report. Finalize Observations, Recommendations, Suggestions and Good Practices		Venue: Individual Work: *Hotel Ripa Roma* Module Leaders with Module reviewers
Sunday 27 November 2016		
Rest day		
	Cultural programme	Visit to *Capitolini Museums* and *Roman Forum*
Monday 28 November 2016		
Daily Discussions		
08:00–22:00	Report writing	ISPRA Conference Room 7th floor Building B The IRRS team + LO.
12:30–13:30	Lunch	
13:30–18:00	Continue report writing	ISPRA Conferene Room 7th floor Building B
Tuesday 29 November 2016		
08:00–12:00	Finalize report text	TL, DTL, TC and DTC
12:00	Draft to be sent to ISPRA for review	
Wednesday 30 November 2016		
08:30–16:00	ISPRA review the draft report.	ISPRA Conference Room 7th floor

[2] Counterparts need to introduce the topic and their concern for all Policy Discussions.

IRRS MISSION PROGRAMME		
		Building B
16:00 –	IRRS Team review ISPRA comments	IRRS team + LO
	Finalize Executive Summary and send to OPIC	TL, DTL, TC and DTC
Thursday 1 December 2016		
08:30–12:00	Discussion with the counterparts on findings if required	IRRS Team + Modules counterparts.
12:30–13:30	Meet with Secretary of State	TL, DTL, TC and DTC
12:30–13:30	Lunch	
13:30–14:30	Report finalization by the team	ISPRA Conference Room 7th floor Building B Participants: the IRRS
Friday 2 December 2016		
09:00–11:00	Handover the report to ISPRA IRRS Exit meeting, Closing remarks by IAEA Official	ISPRA Conference Room Building A
11.00–12:00	Main findings of the IRRS mission Remarks by ISPRA and response to the Mission findings	Team Leader ISPRA Official
	Press Release	IAEA Officials, TL, Government Official, ISPRA Management

APPENDIX V SITE VISITS

1. Medical Installation – Gemelli Hospital
2. TRIGA Research Reactor at Casaccia Center
3. Nucleco Waste Management Facility at Casaccia Center
4. Garigliano NPP

APPENDIX VI RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	R1	The Government should continue its efforts to develop a national policy and strategy for safety and include provisions for human and financial resources, the promotion of leadership and management for safety, including safety culture.
		R2	The Government should elaborate on the national policy and strategy for developing and maintaining the necessary competence nationally for ensuring safety.
		R3	The Government should provide the regulatory body with sufficient competent staff for the proper and timely implementation of its assigned responsibilities.
		S1	The Government and regulatory body should consider revising existing provisions to ensure more effective coordination of the regulatory functions where appropriate.
		R4	The Government should make provisions to ensure that organizations taking protective actions to recover and manage orphan sources have access to the necessary funding to fulfil their functions.
		R5	The Government should complete its policy and strategy for decommissioning and management of radioactive waste, including disposal.
		R6	The Government should enact implementation provisions to ensure

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			that technical services with significance for safety are qualified and authorized.
2.	**GLOBAL SAFETY REGIME**	S2	The regulatory body should consider developing arrangements for identifying, analysing and disseminating lessons learnt from national and international operating and regulatory experience feedback in a more structured and systematic way.
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	R7	The regulatory body should establish a process for developing and maintaining the necessary competences and skills of its staff.
		R8	The regulatory body should obtain technical or other expert professional advice as necessary in support of its regulatory functions provided that adequate financial resources are made available.
		R9	The Government should enact the decrees on the establishment of the national register of radiation sources and national records of doses from occupational exposure and the regulatory body should ensure their implementation.
		R10	The Government should enact specific provisions to foster consultation of interested parties in relevant licensing processes. The regulatory body should define a strategy and improve its processes and plans for communication and consultation with the public and other interested parties, on radiation risks associated with facilities and activities, and on the implementation of its regulatory functions.
4.	**MANAGEMENT SYSTEM OF**	R11	The regulatory body should establish, implement and continuously

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	THE REGULATORY BODY		improve an integrated management system in line with IAEA Safety Standards.
		S3	The regulatory body should consider developing a plan for the establishment and implementation of the integrated management system where, among others, key priorities are pointed out, and interactions between the processes are defined.
		R12	The management system of the regulatory body should be developed so as to foster, in a documented manner, a strong safety culture and provide structure and direction in a way that permits and promotes the development of such a culture.
5.	**AUTHORIZATION**	S4	The regulatory body should consider the verification of technical skills in the process of renewing operators Certificates of Qualification for nuclear facilities.
		S5	The regulatory body should consider establishing safety requirements for a research reactor in long term shutdown.
		S6	The regulatory body should consider ensuring that the Safety Analysis Report has to be revised also as a result of the periodic safety reviews so that it reflects its actual status.
		R13	The Government should ensure that disposal facilities for radioactive waste are developed, operated and closed in a series of steps (site selection and evaluation, facility design, construction, operation, closure, institutional control). Each of these steps should be supported, as necessary, by iterative evaluations of the safety of the

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			disposal system. In particular the legislative provisions should envisage separate authorizations for different stages in the lifetime of the facility and adequate time periods for regulatory review and assessment.
		S7	The regulatory body should consider applying a graded approach within the authorization of radiation sources.
		R14	The Government should review the legal framework for authorization of radiation sources in order to introduce, in relation to the risk of the installation, a mechanism which include a series of steps (e.g. facility design, construction, operation, closure) to be consistent with IAEA Safety Standards and taking into account the graded approach.
		R15	The Government should ensure the consistency in the authorization process of category B sources.
		S8	The regulatory body should consider requiring an independent verification of the safety assessment, as appropriate taking into account a graded approach, for radiation sources before it is submitted to the regulatory body.
		R16	The Government should establish provisions for the preparation of decommissioning plans, in accordance with IAEA safety standards, for new and for existing facilities that have not submitted a decommissioning plan.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		GP1	The use of up to date, state of the art safety standards from foreign regulatory bodies by ISPRA in the field of decommissioning and waste management, in order to cover gaps in the Italian framework, pending further regulatory updates, is considered to be a good practice because it requires a superior performance to what is commonly observed in decommissioning and in the on-site design, construction and operation of waste treatment facilities.
		R17	The Government should review and accordingly revise the authorization process for carriers regarding the: - legal responsibilities and needs of involved parties - specification of conditions for authorization - implementation of a graded approach - consistency with exemption requirements for authorization based on SSR-6 to achieve a transparent, effective and simplified authorization process for all modes of transport.
		S9	ISPRA should consider specifying in their Package Design Approval Certificates that the date of the next maintenance or servicing operation, according to the approved maintenance or servicing programme, should be indicated on the packaging.
		GP2	The development, maintenance and use of the comprehensive ISPRA web-based database (TRARADWEB) is considered to be a good practice because it goes beyond the collection of standard transport data by providing additional safety related data and corresponding analyses tools necessary to perform dose assessments due to transport, to identify non-compliances and to support the provincial

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			emergency preparedness and planning.
6.	**REVIEW AND ASSESSMENT**	R18	The regulatory body should establish specific requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct appropriate safety assessments.
		R19	The regulatory body should establish formalized procedures to specify the principles, requirements and associated criteria for safety upon which its regulatory review and assessment is performed and for recording the results.
		R20	The regulatory body should require the operators of research reactors to perform periodic safety reviews of all factors of relevance for safety according to a graded approach.
		R21	The regulatory body should establish and maintain an appropriate training and qualification programme to assure that the future needs regarding the review, assessment and approval of package designs for transport of spent fuel and high level vitrified waste are met.
7.	**INSPECTION**	S10	The regulatory body should consider complementing its programme for inspection of facilities and activities so as to better implement a graded approach including both announced and unannounced inspections.
		S11	The regulatory body should consider implementing defined inspection procedures.
		R22	The regulatory body should develop a plan for increasing the number

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			of staff with the required competencies to be nominated as inspectors, so that inspections of facilities and activities are performed and are commensurate with the associated radiation risks.
		S12	The competent authority should consider reviewing the consignor's Certificate of Compliance for consistency with the IAEA safety standards.
8.	**ENFORCEMENT**	S13	The Government should consider attributing further enforcement powers to the regulatory body in order that the response to the non-compliances, is in accordance with a graded approach.
9.	**REGULATION AND GUIDES**	R23	The regulatory body should develop and implement processes for establishing, adopting, promoting and amending guides.
		R24	The regulatory body should complete the issuing of specific guidance on the content of the documents to be submitted by the applicant in support of an application for authorization for decommissioning, radioactive waste management including disposal, research reactors, transport, radiation source facilities and activities.
		R25	The regulatory body should establish requirements on research reactor operational programmes for ageing management and for the use of feedback from operating experience.
		R26	The regulatory body should complete the existing requirements for decommissioning and should update and/or establish the requirements for radioactive waste management facilities and

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			activities, including disposal.
		R27	The Government should assign the competent authority for all modes of transport of radioactive materials and define the responsibilities and duties in the national legal framework as required in the IAEA Transport Regulations SSR-6.
		R28	The Government should establish a systematic process for reviewing and revising transport regulations to keep them up to date, in which feedback is taken into account and interested ministries and competent authorities establish a consultation process with organizations representing applicants and users within the field of safe transport of radioactive material.
		S14	The Government should consider establishing a national advisory committee to perform the review and revision processes.
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R29	The Government, in cooperation with the regulatory body, should establish legislation and guidance that clearly define specific requirements on emergency preparedness and response commensurate with the risk in consistency with the IAEA safety standards.
		S15	ISPRA should consider establishing internal arrangements in order to involve as appropriate NECS in the process of reviewing and assessing applications for authorization.
		S16	The regulatory body should consider using the internationally recommended Emergency Preparedness Categories (EPC) in order to

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			provide a consistent advice to Civil Protection Authorities, applying a graded approach.
		R30	The Government should ensure that an emergency classification system is established that accounts for the requirements of IAEA safety standards.
		R31	The Government should ensure that operational criteria, including operational interventional levels, are established as appropriate, in order to effectively take early protective actions and other response actions in case of a nuclear or radiological emergency.
		R32	The regulatory body should develop and implement procedures for the selection of personnel and for training to ensure that the personnel selected have the requisite knowledge, skills and abilities to perform their assigned response functions.
11.1	**OCCUPTIONAL RADIATION PROTECTION**	GP3	The Italian system of education and training for qualified experts is of outstanding high quality and is exemplary in radiation protection.
		R33	The Government and the regulatory body should establish a process to introduce the use of dose constraints in the optimization for protection and safety of workers.
11.2	**CONTROL OF RADIOACTIVE DISCHARGES, MATERIAL FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS**	R34	The regulatory body should assess the total public exposure due to authorized sources and practises in the State.
		S17	The regulatory body should consider publishing at national level results from source monitoring and environmental monitoring

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION		programmes and dose assessments.
		R35	The Government should ensure that appropriate reference levels are established and that a protection strategy for existing exposure situations is established and implemented. The regulatory body should periodically review the appropriateness of the reference levels.
		R36	The Government should ensure that a provision is made in the framework for protection and safety for an appropriate national system of records covering all the data gathered before, during and after remediation, in line with IAEA Safety Standards.
		R37	The Government should extend the mapping of activity concentrations of radon in dwellings and should review, establish and implement the action plan for controlling public exposure due to radon indoors.
		R38	The regulatory body should establish specific reference levels for exposure due to radionuclides in commodities.
12.	**INTERFACE WITH NUCLEAR SECURITY**	None	

APPENDIX VII REFERENCE MATERIAL USED FOR THE REVIEW

1.	Act 28 April 2015 No. 58
2.	Act 31 December 1962 No. 1860
3.	Decree of the Ministry of Environment and Protection of Land and Sea and of the Ministry of Economic Development - 7 August 2015
4.	Decree of the President of the Council of Ministers 10 February 2006 D.P.C.M. 10
5.	Italian Legislation on Nuclear Safety and Radiation Protection
6.	Legislative Decree 15 February 2010 No. 31
7.	Legislative Decree 17 March 1995 No. 230
8.	Legislative Decree 4 March 2014 No. 45
9.	Legislative Decree 6 February 2007 No. 52
10.	List of relevant national legislative documents and technical guides together with the translation of the most relevant ones
11.	Declaration of Quality Policy
12.	Convention of Nuclear Safety 7th Italian National Report
13.	Joint Convention Fourth Italian National Report
14.	Technical Guide No. 11 - Criteria for the compilation of Information Reports on the Operation of Nuclear Power Plants to be Sent to ENEA
15.	Technical Guide No. 26 - Radioactive Waste Management
16.	Technical guide No. 29 – Siting criteria for a near surface disposal facility for low and intermediate level radioactive waste
17.	Technical Guide No. 4 - Implementation Of The Article 42 Of Decree N° 185. Detailed Construction Plants
18.	ARM Part 1
19.	ARM Part II
20.	Draft Action Plan

21.	General Information on the Nuclear Programme relating to Modules 1 to 12
22.	General information on the decommission operations at the main nuclear installations
23.	Inspection Assignment form
24.	ISPRA Internal documentation
25.	Example of ISPRA Technical Report Content for the approval of a detailed project
26.	Examples of Authorization and Approval documents
27.	Introduction to Policy Issues

APPENDIX VIII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1(Rev 1) (Vienna2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY- Leadership and Management for Safety, General Safety Requirements 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 GSR Part 3, (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 Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities General Safety Requirement Part 6, No. GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency General Safety Requirement Part 7, No. GSR Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material Specific Safety Requirements 6, No. SSR 6, IAEA, Vienna (2012).
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
13. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
14. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
15. 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)
16. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
17. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)

18. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)

19. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)

20. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)

21. 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)

22. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste Specific Safety Requirements 5, No. SSR 5, IAEA, Vienna (2011)

APPENDIX IX ORGANIZATION CHART