



**INTEGRATED
REGULATORY
REVIEW SERVICE (IRRS)**

MISSION

TO

The Russian Federation

Moscow

16 to 27 November 2009

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY





**INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
REPORT TO
THE GOVERNMENT OF THE RUSSIAN FEDERATION**

*Moscow, Russian Federation
16 to 27 November 2009*





INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
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THE GOVERNMENT OF THE RUSSIAN FEDERATION

Mission date: *16 to 27 November 2009*

Regulatory body: *Rostechnadzor and the Ministry of Natural Resources and Environment*

Location: *Moscow, Russian Federation*

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

Organized by: *International Atomic Energy Agency (IAEA)*

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The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

EXECUTIVE SUMMARY

At the request of the Government of the Russian Federation, an international team of twenty two experts in nuclear, radiation, radioactive waste and transport safety visited the Ministry of Natural Resources and Environment (hereafter referred to as MNRE) from 16 to 27 November 2009 to conduct an Integrated Regulatory Review Service (IRRS) mission.

The purpose of this IRRS mission was to review the framework for regulating safety of all nuclear facilities and activities and radioactive sources in the Russian Federation and the effectiveness of regulatory functions implemented by MNRE and by the Federal Environmental, Industrial and Nuclear Supervision Service of Russia (hereafter referred to as Rostechnadzor). The review was carried out by comparison against IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS Review Team and the Russian counterparts in the areas covered by IRRS.

The IRRS Review Team consisted of 18 senior regulatory experts from 15 Member States, four staff members from the IAEA and an IAEA administrative assistant. The IRRS Review Team carried out the review in all relevant areas: responsibilities and functions of the Government, 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, and the development of regulations and guides.

The IRRS review addressed regulation of nuclear power plants, research reactors, waste management facilities, fuel cycle facilities, industrial and medical sources, and research facilities and activities. The review also addressed selected aspects of the Code of Conduct on the Safety and Security of Radioactive Sources and the transport of radioactive material. Recognizing the importance of the forthcoming law on Radioactive Waste Management for the Russian Federation, the IRRS Review Team did not review in detail the existing regulatory framework concerning the legacy radioactive waste management facilities and activities.

The mission included observations of regulatory activities and a series of interviews and discussions with key MNRE and Rostechnadzor personnel. In order to help assess the effectiveness of the regulatory inspection system, the IRRS Review Team also interviewed staff of other organizations on visits to the Kalinin NPP, the Mayak plant, the MEPHI research reactor, the Moscow radon waste management facility, the Nuklon facility, and Rostechndazor's technical support organization Scientific and Engineering Center for Nuclear and Radiation Safety (SEC NRS).

MNRE and Rostechnadzor provided the IRRS Review Team with substantial documentation as advance reference material and results of an extensive self-assessment, including a report with conclusions and an action plan with measures to improve its regulatory effectiveness. The IRRS Review Team recognizes the importance of the action plan and supports its full implementation in a timely manner.

Throughout the mission, the IRRS Review Team was extended full cooperation in technical regulatory and policy discussions with MNRE and Rostechnadzor management and staff. The IRRS Review Team identified a number of good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions.

The IRRS Review Team noted that a comprehensive nuclear regulatory framework including regulatory organizations is in place in the Russian Federation. As part of implementing the State policy in nuclear and radiation safety assurance, a new organizational structure was established on 29 May 2008, putting Rostechnadzor under the jurisdiction of the Ministry of Natural Resources and Environment (MNRE). The IRRS Review Team expects that the Ministry will provide strong support within the Government to

Rostechnadzor in stabilizing the regulatory structure and making nuclear and radiation safety regulation in the Russian Federation more effective.

The good practices of this system as identified by the IRRS Review Team are:

- The extensive use of the IAEA Safety Standards in developing the nuclear and radiation safety regulations and guides of the Russian Federation.
- The periodic certification of Rostechnadzor supervisors and managers by an internal council.
- Rostechnadzor's approach to assess the competence of managers and upper level technical staff of nuclear power plants.
- Provision of good record keeping of the radioactive sources inside the Regulatory Authority Information System which is based on the corresponding IAEA system.
- A comprehensive and detailed set of records describing the current situation at the nuclear facilities.

The IRRS Review Team identified some priority issues in need of improvement and believes that consideration of these items would enhance the overall performance of the regulatory system:

- Legislation on nuclear and radiation safety requires enhancement to provide for effective and sustainable regulation for the use of nuclear energy in the Russian Federation. Several legislative actions are already underway, and the importance of these actions is emphasized by MNRE and Rostechnadzor in their joint action plan. Among the various actions of the joint action plan, special attention should be paid to: the removal of restrictions in performing inspections, implementing the law on radioactive waste management and developing regulations for decommissioning.
- A policy issue that requires special attention is the need to provide additional resources to Rostechnadzor, especially in view of the ongoing programme for construction of new nuclear power plants and the necessity that continued strong regulatory oversight of existing nuclear and radiation facilities not be undermined.
- Sustainable solutions are needed in legislation to confirm adequate financing of the independent safety review and assessment of licence applications, and to provide a means for recruiting and maintaining adequate competent staff in Rostechnadzor. In addition, Rostechnadzor should develop a programme for ensuring the continued objective and fully independent assessment of nuclear facilities safety performance by site inspectors.
- Improved coordination of MNRE and Rostechnadzor with other involved regulatory authorities needs to be ensured especially for optimization of radiation protection, regulation of radioactive discharges and releases to the environment, and fire protection.

The IRRS Review Team findings are summarized in Appendix V.

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

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I. INTRODUCTION

At the request of the Government of the Russian Federation, an international team of twenty two experts in nuclear, radiation and radioactive waste safety visited the MNRE from 16 to 27 November 2009 to conduct an Integrated Regulatory Review Service (IRRS) mission to review the Russian nuclear regulatory framework and its effectiveness. In November 2008, a preparatory meeting had been carried out in Moscow to discuss the objective and purpose of the review as well as its scope in connection with all aspects of the work of MNRE and Rostechnadzor.

The IRRS Review Team consisted of 18 senior regulatory experts from 15 Member States, four staff members from the IAEA and an IAEA administrative assistant. The IRRS Review Team carried out the review of the MNRE and Rostechnadzor in all relevant areas: responsibilities and functions of the Government, 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, and the development of regulations and guides.

The IRRS review addressed facilities and activities regulated by MNRE and Rostechnadzor, including the operation of nuclear power plants, research reactors, waste management facilities, fuel cycle facilities; and industrial, medical and research facilities and activities. The review also addressed implementation of the Code of Conduct on Safety and Security of Radioactive Sources, and the transport of radioactive material. Emergency preparedness was not included in the IRRS scope.

In addition, policy issues were addressed, including: “State Policy in the field of safety assurance of the use of nuclear energy, preparation and issuing of safety regulations, independence of the regulatory decision making on safety issues, resources and financing of regulatory work, national strategy and program for nuclear waste management”.

MNRE and Rostechnadzor prepared substantial documentation as advance reference material and a well prepared self-assessment, including a report with conclusions and an action plan with measures to improve its regulatory effectiveness. During the mission the IRRS Review Team performed a systematic review of all topics using the advance reference material, held interviews with MNRE and Rostechnadzor management and staff and performed direct observation of the working practices during inspections carried out by Rostechnadzor.

The mission included observations of regulatory activities and a series of interviews and discussions with the staff of other organizations to help assess the effectiveness of the system. These involved the Kalinin NPP, the Mayak plant, the MEPHI research reactor, the Moscow radon waste management facility and the Nuklon facility.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Russian nuclear regulatory framework and regulatory activities as applied to all regulated sources, facilities and activities, to review its regulatory effectiveness and to exchange information and experience in the areas covered by IRRS. The review was carried out by comparison against IAEA safety standards (Appendix VI) and the Code of Conduct on the Safety and Security of Radioactive Sources as the international benchmark for safety. Following the endorsement by the IAEA Commission for Safety Standards (CSS) of the new Safety Requirements for Governmental, Legal and Regulatory Framework for Safety (IAEA Safety Standards Series No. GSR Part 1) in October 2009, it was agreed with MNRE that this document would be used as a main reference and as the basis for the structure of the report.

It is expected that the IRRS mission will facilitate regulatory improvements in the Russian Federation and throughout the world from the knowledge gained and experiences shared by MNRE and Rostechndzor and the IRRS reviewers and through the evaluation of the effectiveness of the Russian nuclear regulatory framework and its good practices.

The key objectives of this mission were to enhance nuclear and radiation safety and nuclear security by:

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Russian government authorities, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 26 to 28 November 2008. The preparatory work for the mission was carried out by the appointed Team Leader Mr Jukka Laaksonen, Director General of the Finnish regulatory body (STUK), the Deputy Team Leader Mr Ramzi Jammal, Vice President of the Canadian Nuclear Safety Commission (CNSC), the IRRS IAEA Team Coordinator Mr Gustavo Caruso, and the IRRS IAEA Deputy Team Coordinator Mr Hilaire Mansoux.

The IRRS Review Team had extensive discussions regarding regulatory programmes and policy issues with the senior management of MNRE and Rostekhnadzor represented by Mr Semen Levy, Deputy Minister of Natural Resources and Environment of the Russian Federation, Mr Igor Shumakov and Mr Andrey Peschkov from the Department for International Cooperation of the MNRE, representatives from the department of state policy and regulation in the area of technological and nuclear safety of MNRE, Mr Valery Bezzubtsev, Deputy Head of Rostekhnadzor and some of its staff, Mr Boris Gordon, director of the Scientific and Engineering Centre for Nuclear and Radiation Safety (SEC-NRS) and some of its staff.

The Liaison Officer for the IRRS mission was Mr. Andrej Peshkov, The discussions resulted in the following areas to be covered by the IRRS mission:

- Nuclear power plants;
- Research reactors;
- Fuel cycle facilities;
- Waste management facilities;
- Medical, industrial and research facilities and activities;
- Transport of radioactive materials;
- Selected policy issues.

In addition, it was decided that the Code of Conduct for the Safety and Security of Radioactive Sources would be included.

Mr Semen Levi and Mr Valery Bezzubtsev made a comprehensive presentation on the newly established relationship and main responsibilities of MNRE and Rostekhnadzor and current activities and regulatory challenges. IAEA presented the IRRS principles and methodology, including the self-assessment phase. This was followed by a discussion on the work plan for the implementation of the IRRS in the Russian Federation before the end of 2009.

The proposed IRRS Review Team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS Review Team was confirmed. Logistics including meeting and work space, counterpart identification, lodging and transportation to accommodate site visits and observations were also addressed.

MNRE and Rostekhnadzor initiated the self-assessment phase of the IRRS in January 2009. In April 2009, a workshop on self-assessment was organized in Moscow in order to:

- review the self-assessment status and measure the progress made for each of the IRRS topical areas,
- provide feedback from the IAEA and discuss the most effective implementation of the self-assessment process, based on the IAEA methodology and experience;

- review sample answers to self-assessment questionnaires (for selected topical areas, which were finished by MNRE and Rostechнадзор) and to discuss IAEA expectations regarding the answers and quality of the substantiating information;
- develop and agree on a joint action plan identifying actions and deadlines for all activities to be conducted by the Russian Federation and the IAEA, during the period from May to November 2009 in preparation for the IRRS mission.

In August 2009, MNRE invited the IRRS Team Leader, Deputy Team Leader, Coordinator and Deputy Coordinator to present them the complete result of the self-assessment and to finalize the preparation of the mission.

In September 2009, MNRE provided IAEA with the advance reference material for the review, including the self-assessment report and associated draft action plan.

B) REFERENCE FOR THE REVIEW

The most relevant IAEA safety standards used as review criteria are: GS-R-1, Safety Requirements on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety Requirements, published 2000; GSR Part 1, Safety Requirements on Governmental, Legal and Regulatory Framework for Safety (revision of GS-R-1, endorsed by the Commission on Safety Standards in October 2009); GS-R-3, Safety Requirements on The Management System for Facilities and Activities; the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS); and the Code of Conduct on the Safety and Security of Radioactive Sources.

The complete list of IAEA publications used for this mission is given in Appendix VI

C) CONDUCT OF THE REVIEW

An opening IRRS Review Team meeting was conducted on Sunday, 15th November 2009 in Moscow by the IRRS Team Leader, the IRRS Deputy Team Leader, the IRRS IAEA Team Coordinator and the IRRS IAEA Deputy Team Coordinator to discuss the specifics of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers.

The opening remarks were given by Mr. Igor Shumakov, special advisor to the Minister of Natural Resources and the Environment. The Liaison Officer, Mr. Andrey Peshkov, was present at the opening IRRS Review Team meeting, in accordance with the IRRS guidelines. The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 17th November 2009, with the participation of MNRE, Rostechнадзор, and SEC-NRS senior management. Opening remarks were made by Mr. Semen Levy, Deputy Minister, the IRRS Team Leader and the IRRS Deputy Team Leader.

During the mission, a systematic review was conducted for all the review areas with the objective of providing MNRE and Rostechнадзор with recommendations and suggestions as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to relevant organizations and direct observations regarding the national practices and activities.

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

The IRRS exit meeting was held on Friday 27th November 2009. The opening remarks at the exit meeting were presented by Mr Semen Levi. The results of the IRRS mission were presented by Mr Jukka Laaksonen. The closing remarks were made by Mr Philippe Jamet, Director of the Division of Nuclear Installation Safety of the IAEA Department of Nuclear Safety and Security and Deputy Ministry Levi, from the MNRE.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY

State policy is defined in the decree of the President, No. Pr-2196 dated 04.12.2003, “Fundamentals of the national policy in nuclear and radiation safety assurance in the Russian Federation or the period of up to 2010 and beyond”. This policy emphasizes the need to strengthen and improve the regulatory body.

As part of implementing the State policy, a new organizational structure for nuclear and safety regulation was established on 29.05.2008, putting the Federal Environmental, Industrial and Nuclear Supervision Service of Russia (hereafter referred to as Rostekhnadzor) under the jurisdiction of the Ministry of Natural Resources and Environment of the Russian Federation (hereafter referred to as MNRE). The IRRS Review Team expects that the Ministry will provide strong support within the Government to Rostekhnadzor in stabilizing regulatory activities and to make safety regulation in the Russian Federation more effective.

The IRRS Review Team assessed the commitment of the Government to ensuring nuclear safety on the basis of two global indicators: the state of development respective legislation and the status of implementation of nuclear and radiation safety regulation.

As affirmed in the Convention of Nuclear Safety (CNS), effective regulatory activities are an important element for ensuring nuclear safety. According to the CNS, each Contracting Party shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework, and provided with adequate authority, competence and financial and human resources to fulfil its assigned responsibilities.

As a lesson learned from the Chernobyl accident that took place in the former USSR in 1986, there has been very significant progress in developing a regulatory regime in the Russian Federation. The IRRS Review Team noted that there is regulatory basis in the Russian Federation and the corresponding regulatory organization. Important needs for further development have been identified in a self-assessment conducted by the Russian experts before the IRRS mission, and a respective action plan has been developed and has been signed by the Minister of Natural Resources and Environment and by the Head of the Federal Environmental, Industrial and Nuclear Supervision Service.

A specific law on nuclear and radiation safety regulation in the Russian Federation was drafted, however, according to the recommendations of the leading Russian institutions, it was decided to incorporate the necessary articles into the law on the use of atomic energy.

The responsibility for regulating nuclear and radiation safety is assigned to five different state organizations. Taking into account the experience in other countries, a sole responsibility generally strengthens the effectiveness and efficiency of safety regulation. The IRRS Review Team noted a concern on the Articles 23 and 45 of the law No. 170-FZ dated 21.11.1995 “On the atomic energy use”, and a number of Articles (2, 4, 8) of the law No. 317-FZ dated 01.12.2007 “On State Corporation for Atomic Energy Rosatom”, which list Rosatom as a safety regulator although it has a significant role in promotion and utilization of nuclear energy in the Russian Federation. The Russian counterpart informed the IRRS Review Team that a legislative change to remove these articles from the above laws is already in progress.

Major restrictions on the frequency and timing of proactive safety inspections could be imposed by the law No. 294-FZ dated 26.12.2008 “On protection of the rights of legal persons and individual entrepreneurs in exercising governmental oversight and municipal control”, unless the ongoing legislative processes are successful in removing these restrictions. It is recognised that the law No. 294-FZ is intended to reduce the regulatory burden to the commerce in the Russian Federation in general. But it is vital that laws related to nuclear regulation ensure safety is paramount. Frequent and timely inspections are essential in ensuring the safety of hazardous facilities and structures. The conclusions of this report

assume that the legislative processes to eliminate the negative impact of the law No. 294-FZ on nuclear regulation are successful.

In the past, inadequate attention has been given to the safe management of radioactive waste in Russian Federation, but the situation is expected to improve after adopting a law on radioactive waste management that is in the final stage of preparation. The IRRS Review Team noted that the competent regulatory bodies needed for implementing the law and also their tasks in the field of radioactive waste regulation are planned to be identified in a decree by the Government and in the related administrative regulations.

A policy issue that requires special attention is providing necessary human and financial resources to Rostekhnadzor. A major programme for construction of new nuclear power plants has been started in the Russian Federation some years ago. The international experience has demonstrated that significant regulatory resources are needed for the regulatory oversight of nuclear power plant construction. It is important that the need to regulate new construction does not undermine the continued regulatory oversight of existing nuclear and radiation facilities, and therefore the IRRS Review Team would expect to see an appropriate increase in resources for the regulatory body.

The adequacy of human resources available for the nuclear regulatory control is a major concern because many persons with high professional competence are approaching retirement age or are leaving Rostekhnadzor for other reasons. Replacing the lost persons with new staff that has adequate qualifications and experience requires new approaches. An obvious problem is that the net income that can be offered by Rostekhnadzor is not competitive with the income that can be earned in service of the nuclear power industry.

Financing of the independent safety assessment, which is the key part of the licensing process, has significantly improved in the last one and a half years. Rostekhnadzor does not by itself conduct safety review needed for assessing the safety demonstration presented by the licence applicants. This work is generally contracted to SEC-NRS, which is a competent organization with necessary expert knowledge and manpower. Part of these reviews have until now been conducted at the direct cost by the licence applicant. A positive observation is that the safety reviews of most hazardous nuclear facilities such as nuclear power plants have been purchased with the budget funds of Rostekhnadzor. This has helped to ensure the quality of the licensing review and its independent guidance by the Rostekhnadzor.

In the Russian Federation, further enhancement of the legislative basis for a more effective and sustainable nuclear and radiation safety regulation is needed. To achieve this, special attention should be paid to removal of restrictions in performing inspections and implementing the law on radioactive waste management as well as developing regulations for decommissioning.

It is necessary to improve coordination between the regulatory organizations.

The gap in income between the nuclear power industry and the regulatory body is an issue that calls for innovative solutions to be able to recruit and maintain experienced competent staff.

Financing of the independent safety assessment, which is the key part of the licensing process, needs a sustainable solution based on legislation although the situation has significantly improved in the last two and a half years.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 para 2.1 states that *“Facilities and activities cover a broad and diverse range, from the use of a single low energy radiation source to the operation of complex facilities such as nuclear power plants or spent fuel reprocessing plants. The regulatory regime shall be structured and resourced in a manner commensurate with the potential magnitude and nature of the hazard to be controlled.”*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2) **BASIS:** GS-R-1 para 2.2 (1),(3),(4) states that “*There are certain prerequisites for the safety of facilities and activities. These give rise to the following requirements for the legislative and governmental mechanisms of States:*

(1) A legislative and statutory framework shall be established to regulate the safety of facilities and activities.

(3) Responsibility shall be assigned to the regulatory body for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides.

(4) The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities.”

R1 **Recommendation:** The government of the Russian Federation should continue the work on the enhancement of its legislation in accordance with IAEA Safety Standards to provide clear and sustainable nuclear and radiation safety regulations for all nuclear activities, including radioactive waste management, as well as to remove the restrictions on frequency and duration of the inspections of the regulating authorities.

R2 **Recommendation:** The government of the Russian Federation should develop and implement a financing mechanism which ensures adequate resources for nuclear and radiation safety regulation including competent staff and the necessary financing for independent safety reviews that are a prerequisite for licensing decisions, taking into account the increasing amount of nuclear energy utilization in the Russian Federation.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Russian Federation has promulgated a set of laws establishing the regulatory framework in nuclear and radiation safety. Main principal laws defining the safety model of Russian Federation are, among others, as follows:

- Law on the atomic energy use. No. 170-FZ, dated 1995
- Law on the radiation safety of the public. No. 3-FZ, dated 1996
- Law on protection of the environment No. 7-FZ, dated 2002
- Law on the protection of the public and territories from natural and man-induced emergencies. No. 68-FZ, dated 1994
- Law on the special environmental programmes of rehabilitation of radiation contaminated territorial sections. No. 92-FZ, dated 2001
- Law on funding of specially radiation hazardous and nuclear hazardous production facilities and nuclear facilities. No. 29-FZ, dated 1996

This legal framework provides, among others, the following features:

- Safety principles for the protection of the people, society and the environment from radiation risks,
- An authorisation and supervision system for the different facilities and activities included in the scope,
- The assignment of the prime responsibility for safety to the authorised parties,

- The assignment of regulatory responsibilities to five authorities, which constitute the regulatory body,
- Provisions for review, assessment and inspection of facilities and activities,
- Provisions for preparedness for nuclear or radiological emergency,
- An enforcement system in case of violations.

The framework for safety in the Russian Federation is comprehensive, including legal and regulatory elements and the allocation of responsibilities for safety. The IRRS Review Team noted that the definition of the regulatory system is fragmented and contained in many documents with different administrative and jurisdictional level which requires consolidation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part 1 requirement 2 states that <i>“The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.”</i>
(2)	BASIS: GSR Part 1 requirement 2.5 states that <i>“The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety.”</i>
S1	Suggestion: A more clear structure and integration of the legal framework should be considered for better effectiveness of the nuclear regulations, considering the different roles and responsibilities of all involved parties for safety, and more attention should be given to a graded approach to safety considering the wide range of facilities and activities included.

1.3. ESTABLISHMENT OF A REGULATORY BODY

In the Russian Federation, there are five regulatory authorities (excluding Rosatom), which constitute the regulatory body:

- Ministry of Natural Resources and Environment (MNRE), responsible for establishing the state policy pertaining to nuclear safety,
- Rostekhnadzor, which reports to the MNRE,
- Ministry of the Russian Federation for Civil Defence, Emergencies and Elimination of Consequences of Natural Disasters (EMERCOM), which reports directly to the President of the Russian Federation,
- Federal Medical and Biological Agency (FMBA), which reports to the Ministry for Healthcare and Social Development of the Russian Federation,
- Federal Supervision Agency for Customer Protection and Human Welfare (Rospotrebnadzor), which reports to the Ministry for Healthcare and Social Development of the Russian Federation.

The IRRS mission focused on the MNRE and Rostekhnadzor, and thus no specific conclusions were made on the other organizations mentioned above. The activities in the regulation of nuclear, radiation, industrial and fire safety, and separation of power, rights, obligations and responsibilities of the relevant authorities are set in the specific provisions on the state safety regulation bodies.

MNRE is a federal executive body, which exercises the functions on State policy formulation and legal regulation of the state safety in atomic energy use (with the exception of the activities on development, production, testing, operation and utilization of nuclear weapon and military nuclear power systems).

MNRE is responsible for establishment and approval of the legislative and normative documents.

Rostekhnadzor is in charge of environmental, industrial and nuclear supervision, including licensing of facilities and activities. Out of about 11 000 staff members, approximately 1 500 are in charge of nuclear and radiation safety supervision.

EMERCOM is responsible for the State regulation of fire safety in atomic energy use.

FMBA is responsible for the State medical and biological supervision, including radiation safety of the workers in the nuclear facilities and of the public in the vicinity of these facilities. According to the licensing process, sanitary and epidemiological certificate, submitted by FMBA, is a mandatory document that the applicant to a licence for a nuclear or radiological facility has to present to Rostekhnadzor.

Rospotrebnadzor is responsible for the state sanitary and epidemiological supervision, including radiation safety of the workers in all facilities (medicine, industry, science), except nuclear installations (NPPs, RRs, FCFs).

In addition, other competent authorities are also responsible for carrying out regulatory activities relating to nuclear activities, such as the transport of radioactive material. The IRRS Review Team noted that regulatory functions for the safe transport of radioactive material are divided among six regulatory authorities, one of which is Rosatom an operator responsible for atomic energy.

The responsibility for ensuring a safe use of nuclear energy is shared between multiple authorities, which adds to the complexity of the regulatory processes. Coordination of and liaison between the various authorities concerned in different areas related to the regulation in matter of nuclear safety and radiation safety represents a challenge.

EMERCOM and Rostekhnadzor have concluded an Agreement of cooperation and coordination of their activities in the field of supervision of the facilities in issues related to fire protection and emergency preparedness but the scope of that agreement only includes Nuclear Power Plants at the stage of their operation. Extension of the agreement to other facilities would be beneficial.

The IRRS Review Team noted that there was a lack of coordination among the different authorities on the issues related to the supervision of the practical application of the optimization principle (ALARA) in radiation protection. This situation brings to a regulatory system where the supervision on radiation protection is mainly focused on the verification of the dose limits (limitation principle) rather than in a real application of the optimization concept. The IRRS Review Team confirmed this matter during the observations of Rostekhnadzor inspections in different facilities. There is a need for improving the coordination of the issues related to the radiation protection, especially taken into account the responsibilities and functions of the FMBA and Rospotrebnadzor in this matter.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<p>BASIS: GS-R-1 para 4.2 states that <i>“If the regulatory body consists of more than one authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and coordinated, in order to avoid any omissions or unnecessary duplication and to prevent conflicting requirements being placed on the operator. The main functions of review and assessment and inspection and enforcement shall be organized in such a way as to achieve consistency and to enable the necessary feedback and exchange of information. In addition, the authorities responsible for the different disciplines concerned in the regulatory process, such as those responsible for nuclear, radiation, radioactive waste and</i></p>
	<p><i>transport safety, shall be effectively co-ordinated.”</i></p>
(2)	<p>BASIS: SF-1. Fundamental Safety Principles. Principle No. 5, states that <i>“Optimization of protection “Protection must be optimized to provide the highest level of safety that can</i></p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>reasonably be achieved.”</i>
R3	Recommendation: Regarding the special need for the coordination of radiation protection issues, including those related to the practical application of the radiation protection optimization principle, the bilateral agreements between Rostechнадзор on one side, and FMBA and Rospotrebnadzor on the other side, should be encouraged and given a high priority.
S2	Suggestion: The coordination between the different regulatory authorities should go further than developing bilateral agreements. In particular, common actions, such as inspections, could help avoiding conflicting requirements being placed on the authorised parties.
S3	Suggestion: As part of continuous improvement, Rostechнадзор, FMBA and Rospotebnadzor should analyze the experience gained in the practical application of their agreements and, if appropriate, use this experience for the development of a joint proposal to adapt the necessary provisions of the State to better consolidate the coordination approach.
S4	Suggestion: Rostechнадзор is encouraged to extend its cooperation agreement with EMERCOM beyond NPPs to other facilities.

Specific conclusion for transport

From the current legislation of the Russian Federation, it appears clearly that there are various competent authorities (regulatory bodies) in the field of the transport of radioactive material, as summarized in the following table

	Federal Executive Authority	Functions of Competent Authority	Legislative Basis
1.	Ministry of Natural Resources and Environment of Russia (MNRE)	Norms and regulations	Provision on the Ministry of Natural Resources an Environment of Russia, approved by the Government of RF, No. 404, May 28, 2008,
2.	Federal Environmental, Industrial and Nuclear Supervision Service of Russian Federation (Rostechнадзор)	Supervision and control over nuclear and radiation safety and licensing of activities	Decree of the Government of RF, No. 401, July 30, 2004
3.	State Atomic Energy Corporation ‘Rosatom’	Approvals of packages, shipments, special form material, special arrangement etc, according to para. 802 of TS-R-1	Federal Law No. 317-FZ “On State Corporation on Atomic Energy ‘Rosatom’”, December 1, 2007 (clause 7) The Safety Regulations for Transport of Radioactive Material, NP-053-04, October 4, 2004
4.	Ministry of the Russian Federation for Civil Defence, Emergencies and Elimination of Consequences of	Emergency preparedness for elimination of transport accidents	Provision on the EMERCOM of Russia, approved by the Decree of the President of RF, No. 1228, October 21, 2005,

Federal Executive Authority		Functions of Competent Authority	Legislative Basis
	Natural Disasters (EMERCOM)		
5.	Ministry of Transport of Russian Federation	Competent authority in the field of transportation for all classes of dangerous goods	Provision on the Ministry of Transportation of Russia, approved by the Decree of the Government of RF, No. 395, July 30, 2004
6.	Federal Medical and Biological Agency of Russian Federation (FMBA)	Supervision and control over sanitary and epidemiological welfare of personnel, including dose rate measurements required by transport regulations	Provision on FMBA of Russia, approved by the Decree of the Government of RF, No. 206, April 11, 2005 The Safety Regulations for Transport of Radioactive Material, NP-053-04, October 4, 2004

The main regulatory functions for the safe transport of radioactive material are assigned to Rosatom, which is also one of the main nuclear operators in the Russian Federation. This situation may lead to conflict of interest due to the various responsibilities of Rosatom and is not in compliance with IAEA requirement.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GS-R-1 para 4.2 states that <i>“If the regulatory body consists of more than one authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and coordinated, in order to avoid any omissions or unnecessary duplication and to prevent conflicting requirements being placed on the operator. The main functions of review and assessment and inspection and enforcement shall be organized in such a way as to achieve consistency and to enable the necessary feedback and exchange of information. In addition, the authorities responsible for the different disciplines concerned in the regulatory process, such as those responsible for nuclear, radiation, radioactive waste and transport safety, shall be effectively co-ordinated.”</i>
(2)	BASIS: GSR Part 1 Requirement 4 states that <i>“the government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making”</i>
R4	Recommendation: MNRE should take into account that, for improvement and development of the federal legislation and optimization of the structure of the State authorities, it is necessary to consider the issue of effective distribution of all regulatory functions (competent authority approvals) addressed in the IAEA Regulations for the Safe Transport of Radioactive Material, TS-R-1, para 802, namely approval for packages, shipments, special form material, special arrangements etc. between independent federal executive authorities.
S5	Suggestion: MNRE and Rostekhnadzor should take initiative to enhance their cooperation with the Ministry of Transport, EMERCOM and FMBA to avoid the duplication of the functions of competent authorities, e.g. by establishing of a Memorandum of Understanding.

1.4. INDEPENDENCE OF THE REGULATORY BODY

MNRE

MNRE is responsible for implementation of state policy and legal regulation in the field of safety in atomic energy use. MNRE coordinates and supervises activities of subordinate federal agencies and services, including Rostechnadzor.

MNRE is empowered by the legislation of the Russian Federation to adopt regulatory acts within its sphere of competence, including:

- federal codes and standards in the field atomic energy use;
- procedure of issuing permits authorizing the employees of the atomic energy facilities to work in the field of atomic energy use, in accordance with the list of positions approved by the Government of the Russian Federation;
- list and content of the safety related documents required for licensing of nuclear installations, radiation sources, storage facilities of nuclear and radioactive materials, storage facilities of radioactive waste and (or) activities in the field of atomic energy use, as well as the procedure for ensuring adequate expertise for review and assessment of these documents;
- procedure of organization and supervision over the state system of accounting and control of nuclear materials.

Rostechnadzor

Rostechnadzor is an executive body subordinated to the MNRE.

Rostechnadzor has the independence to establish the structure of its regulatory body including staffing at Head Quarters and its regional offices. The IRRS Review Team noted that the approval for the latest organizational change that was proposed by Rostechnadzor to the Ministry was quickly approved by the Minister. Rostechnadzor can also make all financial decisions concerning the use of funds it receives from the state budget.

It is evident that Rostechnadzor has the independence from the ministry as it relates to its regulatory decisions making in the field of its competence. Regulatory decisions rendered by Rostechnadzor can only be overturned in court of law.

The Head of Rostechnadzor communicates directly to the Minister and has direct access to the Minister. The Head is appointed by the Prime Minister of the Russian Federation and can be dismissed only by the Prime Minister.

The IRRS Review Team noted Rostechnadzor staff does not conduct the review and assessment of the application submitted for approval. These submissions vary from a small operator to a large nuclear facility. Rostechnadzor assess applications, but for the technical review and assessment of applications, Rostechnadzor relies on external expert organizations. Thus Rostechnadzor should be capable to assess the results of the review performed by the external TSO, and this requires significant competence and experience from the Rostechnadzor staff.

MNRE and Rostechnadzor are independent regulatory bodies with respect to their regulatory decisions in respective field of competence.

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

Remediation

In relation to the questions on legacy contaminated sites, the IRRS Review Team was informed that there is a need for regulations in this regards that need to be drafted, approved and implemented. There are many facilities which have contaminated land or have been used as test sites for peaceful use of nuclear explosions. There is not any owner of these sites but the new draft law on Radioactive Waste Management is expected to cover all aspects of radioactive waste management including the remediation of contaminated sites. The IRRS Review Team expects that all important issues like the remediation costs and the regulatory responsibility for the remediation, will be established in the legal and regulatory framework after the approval of the new Law.

The IRRS Review Team was informed that some regulations on remediation issues are under development. There is a need for the comprehensive improvement and implementation of a regulatory framework for remediation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: WS-R-5 para 1.12 states that <i>“This Safety Requirements publication applies to the predisposal management of radioactive waste of all types and covers all the steps in its management from its generation up to its disposal, including its processing (pretreatment, treatment and conditioning), storage and transport. Such waste may arise from the commissioning, operation and decommissioning of nuclear facilities; the use of radionuclides in medicine, industry, agriculture, research and education; the processing of materials that contain naturally occurring radionuclides; and the remediation of contaminated areas.”</i></p>
(2)	<p>BASIS: WS-R-3 para 4.7 states that <i>“The legal framework shall provide for appropriate record keeping that covers the nature and extent of contamination, the decisions made prior to and during the implementation of remedial measures, decisions made after remediation and information on verification. The legal framework shall also identify those responsible for these activities.”</i></p>
(3)	<p>BASIS: WS-R-3 para 4.4 states that <i>“It shall be ensured by means of the legal framework that adequate funding mechanisms are available and that responsibilities are assigned for the financing of remedial measures and protective actions to be taken after remediation that are proportionate, manageable and economically sustainable. It shall be ensured by means of the legal framework that provision is made for adequate funding to be available if organizations or individuals are unable to meet their liabilities. In order to help ensure that the remediation is adequately funded, the regulatory body shall identify all those persons or organizations responsible for the contamination and other appropriate persons to finance the remediation. Voluntary co-operation between owners, industry and the community in partnership shall generally be encouraged in preference to regulatory action.”</i></p>
S6	<p>Suggestion: The government of the Russian Federation should develop and implement the necessary legal and regulatory framework for the control and supervision of the remediation to be undertaken for the identified past practices and installations that need remedial actions. This should include the necessary steps to identify all entities responsible for decontamination. The government should set financial requirements and mechanisms for the remediation activities, for clearance from the regulatory control and for the establishment of the institutional control where</p>

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needed.

Orphan Sources

The Ministry of the Russian Federation for Civil Defense, Emergency Situations and Elimination of Consequences of Natural Disasters (EMERCOM) that deals with fire safety and natural disasters is the responsible authority for the detection and for gaining control over “orphan” and lost radioactive sources. Rostekhnadzor supervises the state system of accounting and control of radioactive substances, radioactive waste and physical protection that are the key elements to prevent appearance of orphan sources

In Russian Federation about 150 000 of radioactive sources are used and thus the probability of appearance of orphan source is not negligible. According to the information of Rostekhnadzor in 2008, only in the metal scrap there were 21 cases of discovery of the orphan radioactive sources. Also there were 10 cases of violations in the state system of accounting and control of radioactive substances and radioactive waste.

Rostekhnadzor could be involved in the state system of gaining control of orphan sources in some cases for investigation of discovered orphan sources. It should be noted that, only Rostekhnadzor has competence and knowledge to fulfill such important tasks as:

- providing advice on measures that should be taken in the event of orphan source discovery; submitting information on incidents, abnormal occurrences and other relevant information to the international organizations in accordance with the international treaties, conventions and agreements;
- making available to the public information on incidents and abnormal occurrences;
- providing feedback to improve physical protection according to the results of investigation of the breaches that lead to the appearance of orphan source.

Documented national strategy for gaining control over orphan sources was not found. No procedure of interaction of involved national authorities in the process of gaining established control over radiation sources including discovery of the orphan sources has been established.

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(1)	BASIS: GSR-Part 1 Requirement 1 states that <i>“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.”</i>
(2)	BASIS: Code of Conduct on Safety and Security of Radioactive Sources states that <i>“8. Every State should have in place an effective national legislative and regulatory system of control over the management and protection of radioactive sources. Such a system should: ... (c) include national strategies for gaining or regaining control over orphan sources...”</i>
(3)	BASIS: GS-R-1 para 3.1 states that <i>“In order to fulfil its statutory obligations, the regulatory body shall define policies, safety principles and associated criteria as a basis for its regulatory actions.”</i>
(4)	BASIS: GS-R-1 para 4.2 states that <i>“If the regulatory body consists of more than one</i>

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	<p><i>authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and coordinated, in order to avoid any omissions or unnecessary duplication and to prevent conflicting requirements being placed on the operator. The main functions of review and assessment and inspection and enforcement shall be organized in such a way as to achieve consistency and to enable the necessary feedback and exchange of information. In addition, the authorities responsible for the different disciplines concerned in the regulatory process, such as those responsible for nuclear, radiation, radioactive waste and transport safety, shall be effectively co-ordinated.”</i></p>
S7	<p>Suggestion: MNRE and Rostekhnadzor are encouraged to establish formal cooperation and exchange of information with EMERCOM and other responsible authorities to provide an effective State system for gaining control over orphan radioactive sources. This should be done through clear allocation of responsibilities and definition of mechanisms of coordination and interaction of national competent authorities.</p>

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

Radioactive Waste Management

In the 1950-60's in the former USSR some facilities for the interim storage and “disposal” of radioactive waste were designed and constructed. These facilities were constructed and operated according to the regulations in force at that time. In the present time the Government of Russian Federation has started to improve the policy and strategy for the long term management of radioactive waste and the draft new law on Radioactive Waste Management has been developed and is now under approval process in the Parliament. For this reason and considering the level of the existing current international recommendations on waste safety it was decided to consider these old facilities as “long term storage facilities”. This decision implied some inconsistency, which stem from the fact that facility originally designed as “disposal” does not provide the possibility of retrieval the radioactive waste. Having such inherited situation, at this moment the regulatory body does not have the legal basis to request the radioactive waste operators for defining the final status of waste storage facility.

Rostekhnadzor has already issued a regulation on “Near Surface Disposal of Radioactive Waste. Safety Requirements (NP-069-06)”; nevertheless its application is foreseen for new licensing decisions of facilities based on the coming Law on Radioactive Waste Management. The IRRS Review Team was also informed that some actions and measures to improve the safety of “radon” type facilities had been taken by the operator based on research and scientific work performed by them, although no authorization process had been conducted. It appears that Rostekhnadzor has not been proactive in taking the initiative for requesting the safety justification (safety case and safety assessment) and has not the authority to request remedial action to be taken, when necessary, with focus on the old radioactive waste management facilities.

Radon Enterprises do lot of waste treatment. They are also responsible for radioactive waste storage facilities, which look like near-surface disposal facilities. These storages have not been re-classified as disposal facilities and they are licensed by Rostekhnadzor as interim storage facilities. However, there are no plans for retrieval, treatment and final disposal. The IRRS Review Team decided not to give any recommendation to this problem taking into account the information given by the Russian counterpart during the interview, about the new draft Law for Radioactive Waste Management which is under approval. The law for Radioactive Waste Management is supposed to help to solve this problem with the classification of the status of described facilities. Based on that law, the ownership, financial aspects and

decision on the disposal will be clarified. The implementation of the law will be defined in the action plan developed after approval of the law.

There is a special method used by Russian Federation to dispose short lived intermediate level liquid waste into the deep geological formations, called “Borehole Injection” and it has been practiced at sites as Krasnoyarsk. The IRRS Review Team could not clarify the regulatory basis for the long term assessment of the impacts into the human health and environment and its connection to the safety assessment. The IRRS Review Team had the possibility to have a short look to the Safety Assessment report for the Krasnoyarsk facility, and could not find the clear safety justification for disposal of liquid radioactive waste at that site. That can be considered as an important environmental and safety issue in need of investigation.

The national policy on radioactive waste management is needed in any country. It has to cover radioactive wastes from all sources including civilian and post military activities, and wastes from historic uses of radioactive materials, including naturally occurring radioactive material; it also may include spent nuclear fuel (SNF) management in the case of spent fuel which will not be reprocessed because it is damaged, or for other logistical reasons. This policy should allocate clear responsibilities for all steps in the waste management system: collection, classification, treatment, packaging, transport, interim storage and final disposal.

There is the Federal Targeted Programme on nuclear and radiation safety, approved in 2007 (Nr 484), setting out the policy and strategy, including timeframe for different steps, like establishment of the storage facilities, disposal facilities and programme for high level waste (including the SNF which cannot be reprocessed). This programme sets out the national commitments for the financing of the program, and provides clear responsibilities and strategy with the time frame for meeting the policy goals. The next step will be the development and improvement of the necessary regulatory framework.

In the past, inadequate attention has been given to the safe management of radioactive waste in Russian Federation but a Federal Targeted Programme No. 484-p dated 19.04.2007 “On Ensuring Nuclear and Radiation Safety from 2008 to 2015” is now being implemented and provides a clear way forward. As an important step connected with that programme, the legislative measures in this area are now reaching a successful interim stage. Draft law “On the radioactive waste management” has been sent to Duma, and there is a good consensus on the need to have the proposed text quickly adopted and enacted. The law establishes the national infrastructure, and specifies and assigns the tasks to specific organizations. It is a most useful tool for starting improvement of the situation with respect to radioactive waste management. However, the IRRS Review Team emphasized that in implementing the law the competent regulatory bodies and their tasks in the field of radioactive waste regulation should be identified in a decree by the Government.

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(1)	BASIS: GSR Part 5 Requirement 2 states that <i>“National policy and strategy on radioactive waste management 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.”</i>
S8	Suggestion: MNRE should specify the tasks assigned to Rosatom in order to implement the law on radioactive waste management. MNRE should also promote identification of the

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regulatory responsibilities in all areas included in the law on radioactive waste management.

Decommissioning of Facilities

Rostechnadzor is responsible for licensing of decommissioning of nuclear facilities and the safety supervision during their operation and decommissioning. Nevertheless the IRRS Review Team could not find statutory requirements for elaboration and presentation of an initial decommissioning plan since the design stage of the facility and its periodical revision at established intervals.

The IRRS Review Team was informed that the Federal Law on the Use of Atomic Energy No.170-FZ dated 21st November 1995; articles 33, 34 cover the creation of a fund for decommissioning. There are also regulations for the procedure, contributing sources and operation rules of use of the special foundation to finance the decommissioning of nuclear facilities, radiation sources, nuclear material storage facilities, radioactive substances and radioactive wastes storage facilities and to finance research and development activities intended for validating and enhancing safety of these facilities. These regulations are approved by the Decree of the Government of Russian Federation dated 2nd April 1997 No.367.

The regulatory body does not always require to be informed in advance by the operator on the planned shut down of a facility (except for NPPs) and no requirements are in place for a final decommissioning plan to be submitted within the last two years before the end of the authorized operational activities. Rostechnadzor does not require that the operator develops an adequate maintenance and surveillance programme in the case the deferred dismantling option is adopted for its review and approval. If waste is stored on the site, the regulatory body is not requiring that a revised or new, separate authorization, including requirements for decommissioning, is issued for the facility. There are no requirements in place for the release of a facility or land for unrestricted use. If a facility or land will stay under the regulatory control there is no requirement on how to provide appropriate institutional controls to maintain and to ensure the protection of human health and the environment; these controls are subject to approval by the Regulatory Body. There is no clear sharing of responsibilities assigned for implementing and maintaining these controls. The IRRS Review Team understood that these responsibilities are shared between different regulatory bodies.

There are regulations on decommissioning of nuclear facilities in place, which are enforced by Rostechnadzor. Nevertheless they need to be updated in accordance with the IAEA safety standards. The IRRS Review Team was informed on the need for the elaboration of a national strategy on decommissioning, and on the intention for developing a new law covering all the decommissioning issues of nuclear facilities.

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(1)	BASIS: GSR Part 1 Requirement 10 states that <i>“The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel.”</i>
(2)	BASIS: GSR Part 1 para 2.28 states that <i>“Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and radioactive sources and for the duration of activities. The strategy shall include appropriate interim targets and end states. Radioactive waste generated in facilities and activities necessitates special consideration because of the different organizations concerned and the long timescales that may be involved. The government shall enforce continuity of responsibility</i>

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	<i>between successive authorized parties”.</i>
(3)	<p>BASIS: WS-R-5 par 3.4. states that “<i>The responsibilities of the government include:</i></p> <ul style="list-style-type: none"> – <i>Defining the national policy for decommissioning and for management of the resulting radioactive waste;</i> – <i>Defining the legal, technical and financial responsibilities of organizations to be involved in decommissioning;</i> – <i>Ensuring that the necessary scientific and technical expertise remains available both for the operating organization and for the support of independent regulatory and other national review functions;</i> – <i>Establishing a mechanism to provide and ensure adequate financial resources for safe and timely decommissioning”.</i>
(4)	<p>BASIS: GSR Part 5 Requirement 20 states that “<i>The operator shall develop, in the design stage, an initial plan for the shutdown and decommissioning of the predisposal radioactive waste management facility and shall periodically update it throughout the operational period. The decommissioning of the facility shall be carried out on the basis of the final decommissioning plan, as approved by the regulatory body. In addition, assurance shall be provided that sufficient funds will be available to carry out shutdown and decommissioning.</i>”</p>
R5	<p>Recommendation: The Ministry of Natural Resources and Environment should promote the elaboration and approval of an overall legal and regulatory framework for decommissioning in accordance with the IAEA Safety Standards.</p>

1.7. PROVISION OF TECHNICAL SERVICES

The following technical services can be provided in the Russian Federation to the operating organization in the sphere of nuclear energy use: personnel dosimetry, environmental monitoring, calibration of equipment, training for radiation safety, maintenance of radiation installations and equipment, radioactive waste management, and emergency response.

Requirement 13 of GSR-Part 1, 2.41 says that the regulatory body shall authorize technical services that may have significance for safety, as appropriate. Also paragraph 9 of the Code of Conduct for the Safety and Security of Radioactive Sources says that:” Every State should ensure that appropriate facilities and services for radiation protection, safety and security are available to, and used by, the persons who are authorized to manage radioactive sources. Such facilities and services should include, but are not limited to, those needed for: (a) searching for missing sources and securing found sources; (b) intervention in the event of an accident or malicious act involving a radioactive source; (c) personal dosimetry and environmental monitoring; and (d) the calibration of radiation monitoring equipment.”

Rostekhnadzor authorizes providers of the services for maintenance of radiation installations and equipment and radioactive waste management.

Authorization of other services is made by appropriate state authorities:

- personnel dosimetry, environmental monitoring, calibration of equipment – by the federal service that is responsible for supervision of the accuracy of measurements;
- training for radiation service – by the federal service that is responsible for the supervision of education and training.

Emergency response is provided by emergency teams that are part of emergency-technical centers of Rosatom and do not need specific certification. They operate in accordance with the rules established by the RF Government Ordinance # 761 from 20.06.1997

Services for searching for missing sources and securing found sources belong to EMERCOM and do not need specific authorisation.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR COOPERATION

Article 65 of the Federal Law "International Agreements On the Use of the Russian Federation in the field of atomic energy use" states that if the rules of an international agreement of the Russian Federation will be applicable, and if the international agreement of the Russian Federation has established different rules than those provided in this Federal Law, the rules of the international agreement of the Russian Federation are applied. The legislation of the Russian Federation has a mechanism of implementation of the obligations under the international treaties, conventions and agreements. The IRRS Review Team noted that after the changes introduced in the Russian Federation regulatory structure on 29.05.08 the MNRE and Rostekhnadzor are assigned the leading roles at the review meetings of the Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

Russian Federation also has established cooperation between its regulatory bodies and the regulatory bodies of other countries, as well as with international organizations for the purpose of development of cooperation and information exchange. MNRE and Rostekhnadzor organize and coordinate the cooperation with the respective foreign regulatory bodies and the applicable international organizations.

MNRE with the participation of Rostekhnadzor have established active multilateral cooperation with the IAEA, G8, EU, European Commission, and OECD/NEA.

Rostekhnadzor has established bilateral cooperation with foreign nuclear regulatory bodies, including the respective regulatory bodies of the USA, Germany, Finland, Sweden, France, Norway, Ukraine, Armenia, China, India, and Iran.

The regulatory principles and criteria applied in the Russian Federation take into account internationally endorsed standards and international recommendations. Article 6 of the Federal Law "On atomic energy use" Article 6, Federal codes and standards in atomic energy use, paragraph 4 stipulates that codes and regulations shall take into account the recommendations issued by the international organizations cooperating which the Russian Federation in the atomic energy use, especially those of the IAEA.

Regulatory document RD 03 42 97 (article 7) The System of the regulatory documents established by the regulatory body (RD-03-42-97), article 7, states that when developing the federal codes and standards, it is necessary to take into account, among other things: the assurance of completeness and consistency of their requirements; the compliance of their requirements with the state-of-the-art science and technique and to consider domestic and foreign experience in safety regulation when using atomic energy and the experience coming from other state safety regulation bodies in atomic energy use

It was recognized by the IRRS Review Team that Russian Federation supports a broad application of the IAEA Safety standards in its regulations and guides and also in the development of its regulatory functions.

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| (1) | BASIS: GSR-Part 1 Requirement 33 states that <i>“the 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 technical standards and of relevant experience gained....para (4.61) “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 ain the development of the regulations and guides, with account taken of internationally agreed standards and the</i> |
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	<i>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.</i>
G1	Good Practice: The Russian Federation is making an extensive use of the IAEA Safety Standards in developing its regulations and guides.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Sharing of operating experience among the nuclear power plants that operate in the Russian Federation is organized through a dedicated organization called VNIIAES that functions under Rosenergoatom, the operator and owner of all plants. VNIIAES also takes care of the international exchange of operating experience, and the nuclear regulatory organizations are not directly involved in this exchange.

It became apparent from the self-assessment conducted by Rostechнадзор, as well as from discussion of the IAEA experts with the regulatory body counterparts, that presently there are no regulatory requirements in force that would give a framework for a systematic feedback of experience collected during operation of nuclear research facilities. Although certain information (like e.g. decommissioning data) are being collected by Rostechнадзор in an organized way, lack of such a regulation makes the availability of the data uncertain.

Collection and feedback of operational experience is organized for the nuclear power plants in the Russian Federation, but no similar organized activity was found for other nuclear installations, especially for the research reactors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GSR Part 1, Requirement 15 states that <i>“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 their use by authorized parties, the regulatory body and other relevant authorities.”</i>
(2)	BASIS: GS-R-1 para 3.3. states that <i>“In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body:... (7) shall ensure that operating experience is appropriately analysed and that lessons to be learned are disseminated”</i>
S9	Suggestion: Rostechнадзор should evaluate whether its practice in feedback of operating experience is in line with international recommendations and could consider requiring the systematic collection, analysis and dissemination of operating experience of all nuclear facilities, especially for the research reactors.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The regulatory activities of MNRE are carried out through a department in the headquarters. The department has 35 work positions (not all of them filled during the IRRS mission) and its competence includes the issues of nuclear safety (a special division with 6 work positions) as well as safety of construction, power engineering and industry. The department integrating several technical areas on one hand facilitates coordination of complex regulation of safety assurance of nuclear facilities along with other facilities, while on the other hand it leads to dilution of the priority of implementing regulation of nuclear and radiation safety within the background of industrial, construction and energy regulation issues. The activities of the department (in the whole range of its competence) are supported by special assistance divisions in the Legal Department (10 persons) and International Cooperation Department (8 persons). It was noted by the IRRS that the number of staff in the division for safety in nuclear energy use and in the supporting legal department is inadequate to cope with the new tasks in preparation of the federal laws and Government ordinances and in issuance of orders and federal codes and regulations. On the other hand it was noted that technical support to assist in the activities of the Department could be provided by technical expert organizations, first of all the SEC NRS, and also the Rostekhnadzor staff.

The activities of Rostekhnadzor on supervision of nuclear and radiation safety and licensing of activities are carried out through a three-tier supervisory system (1) consisting of the Headquarters Office (about 85 persons), (2), the Regional Offices in 7 Federal regions, and (3) 67 Site Offices (about 1130 persons). Rostekhnadzor employs a total of 11,684 staff. The staffing levels of Rostekhnadzor are defined by the provision of the MNRE issued in 2008, which is intended to ensure that adequate resources are assigned to licensing and supervision activities of all nuclear facilities and activities.

Rostekhnadzor was reorganized in December 2008, to optimize its resources in accordance with the Russian Federation directives. According to Rostekhnadzor's annual report for 2008, the headquarters and regional offices were staffed at 95.7% and 95%, respectively. Staff turnover in these offices was 40% and 15%, respectively, due primarily to staff reductions. These staffing statistics refer to Rostekhnadzor as a whole. With respect to Rostekhnadzor staff in the area of nuclear safety, Rostekhnadzor did not provide specific numbers, but did indicate that there has been an overall increase in the number of staff in this area.

Rostekhnadzor is using industrial inspectors from the field of industrial supervision to supplement its staff supporting the inspection of the new reactor construction program. The technical capabilities of Rostekhnadzor are further strengthened by highly-qualified Technical Support Organizations, such as SEC NRS, that perform safety reviews and assessments of licensing applications, conduct regulatory research, and obtain and exchange scientific information. While Rostekhnadzor approves the Terms of Reference for the safety review to be conducted within the framework of the licensing prior to authorization of a facility or activity, it appears that it may not have sufficient resources in the Headquarters Office to systematically assess the review results given a high number of licences issued in 2008 (1610 licences were granted and 26 were refused).

The self-assessment report prepared prior to the IRRS mission states that the structure and size of Rostekhnadzor are commensurate with its duties and activities. On the other hand, interviews with staff members revealed that remuneration of Rostekhnadzor staff, particularly the site (resident) inspectors, does not allow Rostekhnadzor to be competitive regarding staff recruitment. Aging of Rostekhnadzor staff is a current concern and both MNRE and Rostekhnadzor recognize that this issue needs to be addressed. The importance of this staffing issue is further highlighted by the nuclear staff requirements related to the ambitious NPP construction nuclear programme of the Russian Federation (refer to Section 1.1 for recommendations pertaining to this area).

3.2 STAFFING AND COMPETENCE OF THE REGULATORY BODY

The division for safety of nuclear energy use at MNRE is currently staffed at 50% (3 persons out of 6). Results of two competitions for staffing of the division (held in 2008 and 2009) demonstrated that the current conditions at the Ministry are not competitive to recruit qualified specialists in the nuclear field. Obviously insufficient human resources directly involved in day-to-day activities in regulation of atomic energy use (3 specialists for the whole range of regulation) cause concerns and require adequate response

Some internal training programme is in place in Rostekhnadzor for new entrants in the inspector duties. It is performed as a three months tutorial training with the participation of senior staff members. Tutoring of such a short period of time may only be appropriate for new staff members having previous experience in the nuclear field.

SEC NRS has developed a training programme that could be beneficial to all nuclear safety inspectors, of nuclear facilities but it has not been implemented yet.

The self assessment documentation states that a recruitment strategy and a staffing plan have been elaborated by Rostekhnadzor, whereas no details are given. Furthermore, it was stated by Rostekhnadzor to the IRRS Review Team that there exists an internal certification council for supervisors and managers responsible for nuclear safety. This council certifies the managers and supervisors periodically.

In view of the intensive changeover of the personnel in both the headquarter and the regional offices (as indicated by the Rostekhnadzor annual report) the issue of training is even more pronounced.

Recruitment of new regulatory body staff shall be indispensable in the nearest future. In order to make recruitment of new staff systematic and in line with the requirements based on the nuclear regulatory duties of regulatory bodies, compilation and application of a Competence Matrix would be beneficial. Furthermore, the Systematic Approach to Training as recommended by IAEA, could effectively contribute to the proper training of the staff (both initial training and retraining).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1. Requirement 4.7 states that <i>“In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts”</i>
(2)	BASIS: GS R Part 1 Requirement 18 (4.13) states that <i>“A process shall be established to develop and maintain the necessary competence and skills 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.”</i>
R6	Recommendation: MNRE and Rostekhnadzor should develop and submit to the Government of Russia the Russian Federation a proposal on the human resources required to cope with the nuclear regulatory duties foreseen in relation with construction of the new reactors also in view of the requirement of not jeopardizing the supervision of the safety of existing nuclear facilities.
S10	Suggestion: MNRE and Rostekhnadzor are should develop and implement a systematic approach to training, following the IAEA guidance in this field.
G2	Good Practice: The internal certification council activity is considered as a good practice.

3.3. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

Rostekhnadzor can obtain technical expert support from a number of technical support organizations, mainly from SEC NRS and VO Safety. The areas of expertise include, for example: review and assessment of applicant's safety submission, as part of the licensing process independent safety analysis to verify results presented by applicant; review of the suggested modifications at nuclear facilities; development of regulations; and review of reportable events. Each technical support organization is licenced by Rostekhnadzor for a specific scope of expertise (e.g. design and engineering, review and assessment, etc), based on "Administrative regulations for the Federal, Environmental, Industrial and Nuclear Supervision Service to perform its state function as to licensing of activity in atomic energy use"(AR). The licences are issued to expert organizations for a 10 year period.

The following explanation illustrates the process used, by Rostekhnadzor and SEC NRS, for assigning work and conducting technical reviews and assessments.

Each year Rostekhnadzor collects information from the company licenced to operate NPPs, Energoatom, regarding the volume and scope of work expected to be conducted by the regulatory authority. The information also includes the expected dates of the applicant's/ operator's submission to the regulatory body, as well as the expected duration for receiving the regulatory decisions (e.g. issue of the licence, etc.) The IRRS Review Team was presented with an example of such a document, for 2008, and it was noted that, the average expected duration for a regulatory review of a licence submission (for a new plant) is seven months.

Rostekhnadzor will estimate the necessary amount of work, in person-hours, and based on this will open a tender and a state contract will be awarded to a successful tender, e.g. to SEC NRS. This process is repeated twice per year. The funding for the activities comes in general from Rostekhnadzor budget, but the resources may not always be sufficient. In this case Rostekhnadzor asks the licensee to pay for the review work to be conducted by SEC NRS.

The review work for a specific task is initiated by Rostekhnadzor, whose specialists review the applicant's submission and prepare a document entitled "Technical Assignment". This document contains specific questions related to technical aspects but does not identify specific regulatory requirements and criteria, upon which the applicant's submission should be reviewed. However, Technical Assignment contains a general statement indicating that the review should be conducted based on the applicable laws and federal codes and regulations.

SEC NRS conducts the review and, as necessary, it may use additional external resources, which are not approved by Rostekhnadzor. For each assigned review assignment, SEC NRS assigns a project manager and a coordinator, as well as individual specialists. The work is conducted using SEC NRS procedures, and the output is the review report, which is approved by the senior management and forwarded to Rostekhnadzor. SEC NRS is also allowed to forward a copy of the report directly to the licensee. It should be noted that there is no formally agreed format of the assessment reports produced by SEC NRS, despite the fact that such a format was prescribed by the previous legislation.

Rostekhnadzor reviews the report, as stipulated in section 18.3.311 of AR, and verifies that all items identified in the Technical Assignment are covered and conclusions are clearly stated. Rostekhnadzor does not appear to conduct an independent evaluation of the technical conclusions reached by SEC NRS. However, the IRRS Review Team was informed that Rostekhnadzor specialists participate, during the review process, in some meetings with SEC NRS specialists, if required and the cooperation between the two organizations is proceeding well. Rostekhnadzor communicates its decision, based on the information provided in the assessment report to the licensees, through a formal process, as well as any requests for action to be taken by them. The licence interface process between Rostekhnadzor and SEC NRS, including the regulatory review of the assessment report is not documented.

Rostekhnadzor is making extensive use of its technical support organizations in support of review and assessment. The liaison arrangements are well established in practice, but not formally documented.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: GS-R-1 para 4.8 states that <i>“In undertaking its own review and assessment of a safety submission presented by the operator, the regulatory body shall not rely solely on any safety assessment performed for it by consultants or on that conducted by the operator. Accordingly, the regulatory body shall have a full time staff capable of either performing regulatory reviews and assessments, or evaluating any assessments performed for it by consultants.”</i></p>
(2)	<p>BASIS: GS-R-3 para 5.1 states that <i>“The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved.”</i></p>
(3)	<p>BASIS: GS-R-3 para 5.4 states that <i>“The development of each process shall ensure that the following are achieved:</i></p> <ul style="list-style-type: none"> <i>—Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic requirements, are specified and addressed.</i> <i>—Hazards and risks are identified, together with any necessary mitigatory actions.</i> <i>—Interactions with interfacing processes are identified.</i> <i>—Process inputs are identified.</i> <i>—The process flow is described.</i> <i>—Process outputs (products) are identified.</i> <i>—Process measurement criteria are established.”</i>
(4)	<p>BASIS: GS-R-3 para 5.6 states that <i>“For each process a designated individual shall be given the authority and responsibility for:</i></p> <ul style="list-style-type: none"> <i>—Developing and documenting the process and maintaining the necessary supporting documentation;</i> <i>—Ensuring that there is effective interaction between interfacing processes;</i> <i>—Ensuring that process documentation is consistent with any existing documents;</i> <i>—Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;</i> <i>—Monitoring and reporting on the performance of the process;</i> <i>—Promoting improvement in the process;</i> <i>—Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization.”</i>
R7	<p>Recommendation: Rostekhnadzor should ensure that it has sufficient staff capable of guiding and evaluating independent regulatory reviews and assessments performed by technical support organizations.</p>

Based on the responses to the self-assessment questionnaire and the discussions with the counterparts, related to the formation and use of advisory bodies, the IRRS Review Team noted that there is a legal basis for “the formation and organization of the activity of interdepartmental coordination and deliberative bodies”, in the form of “interdepartmental commissions”, as stipulated in the Decree of the Government of the Russian Federation No. 30 of January 19, 2005. There is a significant number of qualified experts in Russia who could be invited to serve as a member of Rostekhnadzor advisory body, such as experts in the organization in the sphere of Academy of Sciences and in the Ministry of Education.

Currently Rostekhnadzor does not use the services of an advisory body, by which independent advice could be provided to the regulatory body. Based on the requirements of GS-R-1, section 4.9, independent advice should be sought by the regulatory body and the IRRS Review Team considers this to be beneficial for substantiation of regulatory decisions, transparency and independence.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 para 4.9 states that <i>“The government or the regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body; the need or otherwise for such formal advisory bodies is determined by many factors. When the establishment of advisory bodies is considered necessary, on a temporary or permanent basis, such bodies shall give independent advice. The advice given may be technical or non-technical (in advising, for example, on ethical issues in the use of radiation in medicine). Any advice offered shall not relieve the regulatory body of its responsibilities for making decisions and recommendations.”</i>
(2)	BASIS: GSR Part 1 Requirement 20 states that <i>“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.”</i>
S11	Suggestion: MNRE and Rostekhnadzor should consider the establishment of an independent advisory body to support regulatory decision making for substantiation of decisions, transparency and independence.

3.4. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

Communication with the public

According to the IAEA guidance, the regulatory body should promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body. Such communication should include communication on the requirements, judgements and decisions of the regulatory body and the basis for them to the public; providing information on incidents in facilities and activities, including accidents and abnormal occurrences, and other information, as appropriate, available to authorized parties, governmental bodies, national and international organizations, and the public etc. To develop communications certain measures are provided by MNRE and Rostekhnadzor.

In 2008 Public Council under Rostekhnadzor was created. In 2008 it had 2 meetings devoted to nuclear and radiation safety. These addressed review of safety culture and review of public opinion with an objective to improve public relations.

Press-services are functioning at MNRE and Rostekhnadzor. One of the main tasks of these press-services is preparing information about the activities of these organizations for mass media and public.

Important instruments providing communication are websites of MNRE and Rostekhnadzor. They are mainly dedicated to environment protection (MNRE) and industrial safety (Rostekhnadzor) but also include information about nuclear and radiation safety. Especially the Rostekhnadzor site offers useful information including:

- this list of safety regulations (some of them can be accessed from the site);
- administrative regulation;
- list of licences issued for expert organizations (no information about licences for the NPP, waste facilities, radioactive sources etc);

- texts of yearly Rostechnadzor reports (up to 2007),
- texts of reports for supervision activities of territory offices;
- question-answer page (no questions-answers for the nuclear and radiation safety in 2009);
- inspections, sanctions, violations (different regional departments report in different way and only few reports include description of the violation character).

Magazine Nuclear and Radiation Safety is published by SEC NRS. In this magazine articles on safety and draft safety regulations are published. This magazine can be found on the website of SEC NRS. Any interested person can make proposals and comments for the published draft regulations and SEC NRS is obliged to analyse them.

Before the decision on construction of new nuclear facilities is taken, it is required by the law to conduct public hearings about such plans. Four different public hearings were organised last year in Russia, related to plans for construction of new NPPs. While the other regulatory bodies, the Academy of Science and other organizations participated at those hearings, Rostechnadzor did not. At these meetings, the public was informed about the possible radiation risks associated with facilities and activities, and obligations of regulators. From that point of view, Rostechnadzor, as the regulatory body, could be more proactive in its public informational activities and consultation, including setting up of appropriate means to inform interested parties and using all opportunities to demonstrate its role as the regulatory body for radiation and nuclear safety. Among the issues of interest to the general public are risks associated with facilities and activities, the requirements for the protection of the people and the environment, and the processes of the regulatory body.

Information on the MNRE and Rostechnadzor websites could be enhanced by topics such as draft regulations (now they can be found only on the SEC NRS website), texts of all regulations and guides in force, daily/weekly reports about the NPP and other important facilities safety aspects, reports about violations, reports about radiologically significant events (e.g. discovery of orphan sources), measures to improve safety (e.g. campaign for the retrieval of the sources from historical facilities for safe and secure storage that is done now) and other relevant information. The IRRS Review Team noted that it would be useful to create separate pages on the MNRE and Rostechnadzor websites on the nuclear and radiation safety, since at this moment “nuclear” information is lost among the industrial and ecological safety issues.

The general impression is that big efforts are put into one-direction by informing interested parties. However, no information was provided about two-way communications such as workshops for public and mass media, exhibitions, and round tables. MNRE and Rostechnadzor have not analysed their communication efficiency in a systematic manner.

Rostechnadzor puts a lot of effort into communications with interested parties. However, these efforts could be made more systematic and more attention could be paid to the efficiency of communication and especially to a two-way dialogue.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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| (1) | BASIS: GSR-Part 1 Requirement 36 states that <i>“Regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body. The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication and shall hold meetings for informing interested parties and the public and to inform the decision making process.”</i> |
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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S12	<p>Suggestion: MNRE and Rostekhnadzor should conduct a communication efficiency analysis and prepare and implement communications strategy. This should include improvement of the websites by introducing separate and easily found sections for nuclear and radiation safety topics.</p>
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3.5. SAFETY RELATED RECORDS

Radioactive sources record keeping

The State Corporation for Atomic Energy (Rosatom) manages the state system of accounting and control of nuclear material, radioactive substances and radioactive waste (SSAC), including maintenance of appropriate registries and inventories. Radioactive source (RS) accounting is specified to start in respect of Russian-produced RS from the moment of their manufacture (i.e., from delivery to the manufacturer’s finished products storage facility). Accounting of the RS manufactured in other countries start from the time of crossing the Russian Federation customs. Later on, all further sources transfers are registered until the moment of their final disposal to the ultimate storage. Organizations are to notify information to analytical centers on the transfer of the sources. Both the source supplier (after its shipment) and receiver (after its receipt) must submit relevant information. Russian Federation Register of Radioactive Sources is formed in the SSAC of the radioactive substances and radioactive waste. SSAC is regulated by the “Regulations on Organizing System of State Accounting and Control of Radioactive Substances and Radioactive Waste” approved by the Government Decree (1998). Rosatom is the SSAC managing authority at the federal level. In the framework of its authority Rosatom inter alia: organizes information gathering and analysis on accounting and control of radioactive substances and radioactive waste (RW) including forming a register of RS; submits information on the presence and transfer of RS and RW to other state power authorities to the extent necessary to implement their authorities. Currently there are more than 150000 records of radioactive sources in this system.

Rostekhnadzor supervises state systems of accounting for and control of radioactive substances and waste at more than 2300 facilities.

Now Rostekhnadzor is commissioning RAIS (Regulatory Authority Information System) that includes record keeping about the radioactive sources and currently includes about 130000 records. Input of the information both into SSAC and RAIS is based on the information provided by the licensees according to inventory lists.

At this moment there is no interaction between these two systems.

There are two kinds of records keeping for the radioactive sources in Russian Federation. First one is the Register in the SSAC (state system of accounting and control of radioactive material/sources) and the second one is part of the RAIS (Regulatory Authority Information System) that is under commissioning in Rostekhnadzor. Both systems are based on the information provided by the licensee in the form of inventory lists. At this moment there is no interaction between these systems. Interaction between these systems could help to improve the quality of the data and optimize resources needed for the input and check of the data.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<p>BASIS: Code of conduct on the Safety and Security of Radioactive Sources para 11 states that <i>“Every State should establish a national register of radioactive sources. This register should, as a minimum, include Category 1 and 2 radioactive sources as described in Annex 1 to this Code. The information contained in that register should be appropriately protected. For the</i></p>
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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>purpose of introducing efficiency in the exchange of radioactive source information between States, States should endeavor to harmonize the formats of their registers.”</i>
S13	Suggestion: MNRE together with Rostekhnadzor should consider the reasonability and possibility of the use of the information from the register of the state system of accounting and control in the Rostekhnadzor management system RAIS (Regulatory Authority Information System).
G3	Good Practice: Format of the records of the radioactive sources inside RAIS (Regulatory Authority Information System) is the same as in the IAEA RAIS and thus provides possibility of exchange of radioactive source information between the Russian Federation and the IAEA.

Information relating to facilities and activities

During the peer-review and inspection the IRRS Review Team could observe that an extended amount of documentation has been presented and reviewed by Rostekhnadzor and operating organization. There is a lot of documentation which is stored, maintained, reviewed and used by the operating organization and Rostekhnadzor, if needed. Rostekhnadzor has its own records of own documentation, in addition to the documentation developed and stored by the operating organizations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GS-R-1 para 3.3 states that <i>“In order to discharge its main responsibilities,...the regulatory body: (8) shall ensure that appropriate records relating to the safety of facilities and activities are retained and retrievable;..”</i>
(2)	BASIS: GS-R-1 para 3.8 states that <i>“To facilitate compliance with regulatory requirements, the regulatory body has to do the following:.....—Document the procedures that apply to the mechanisms for compliance verification and enforcement;”</i>
G4	Good Practice: The IRRS Review Team recognized as a good practice the existence of such comprehensive and detailed records describing the situation at the facilities.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

Based on discussions between the IRRS Review Team and Rostekhnadzor, it was noted that Rostekhnadzor does not have a comprehensive management system. Rostekhnadzor has in place several elements of a management system, however, these elements are not integrated into one system. The Order of Federal Environment, Industrial, and Nuclear Supervision Service, Number 442, dated June 24, 2008, entitled “Regulation on Quality System of the Federal Environment, Industrial and Nuclear Supervision in the Field of State Safety Control in Atomic Energy Use” (RD-03-29-2008), hereafter referred to as the Order, was established under GAN before Rostekhnadzor became a subordinate to MNRE. Rostekhnadzor stated that although the Order was developed under GAN, its provisions are still relevant to current operations. The Order specifies administrative regulations and procedures to be followed by Rostekhnadzor as it carries out its internal activities with respect to: authorization, compliance, planning, record keeping, and internal quality audits. Given the date of the Order, it does not reflect internal organizational changes made by Rostekhnadzor last year (refer to Section 3.1 in this report). The IRRS Review Team also noted that Rostekhnadzor has not developed a quality declaration or formulated quality objectives, including the methods to achieve the objectives once they have been identified.

With respect to the Order, it contains administrative regulations and procedural provisions, however, there is no description of the management processes necessary to implement these elements of the Order.

The IRRS Review Team also reviewed Rostekhnadzor’s processes for review, assessment, and approval of licensing action requests and modifications, as well as assessment of reportable events to determine their safety significance. The IRRS Review Team noted that even though Rostekhnadzor is authorized to conduct these regulatory activities by various decrees and regulations, it has not developed procedures describing how these activities are to be conducted, including the assignment of work and the review process exercised within Rostekhnadzor upon receipt of products provided by SEC NRS, which performs a significant amount of safety reviews according to the technical assignments of Rostekhnadzor. In addition, the IRRS Review Team noted that other than tracking regulatory actions in a specific area, i.e., review and assessment, inspection, etc., Rostekhnadzor is not tracking the status of regulatory action completion in an integrated manner across all areas for specific nuclear facilities. Furthermore, the IRRS Review Team noted that Rostekhnadzor is not using any type of software tool for tracking the completion status of regulatory actions to inform Rostekhnadzor decisions on regulatory oversight activities.

Rostekhnadzor has not developed and implemented a comprehensive management system to translate the administrative regulations and procedures outlined in the Order into practical application. The Order also does not reflect regulatory body current organizational structure and the regulatory activities it conducts.

In addition, Rostekhnadzor has not developed procedures that describe its current processes for various activities such as review and assessment of licensing action requests, modifications, and reportable events. Rostekhnadzor also has not implemented a system to provide for tracking the current status of regulatory actions in order to determine appropriate regulatory oversight activities going forward.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GS-R-3 para 5.1 states that <i>“The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved.”</i>
R8	Recommendation: MNRE and Rostekhnadzor should establish their respective comprehensive management systems in accordance with IAEA GS-R-3 and amend RD-03-29-2008 in order to reflect current organizational structure. The management system of regulatory

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	body should provide a clear description of the regulatory review and inspection processes, as well as for the analysis of reportable events.
S14	Suggestion: Rostekhnadzor should consider developing and implementing a system capable of tracking the completion status of regulatory actions in order to provide a corresponding regulatory overview.
(1)	<p>BASIS: GS-R-3 para 2.1 states that <i>“A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:</i></p> <ul style="list-style-type: none"> <i>—Bringing together in a coherent manner all the requirements for managing the organization;</i> <i>—Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;</i> <i>—Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.”</i>
(2)	<p>BASIS: GS-R-3 para 3.7 states that <i>“Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization.”</i></p>
S15	Suggestion: Rostekhnadzor should develop a quality declaration that reflects the current activities.

5. AUTHORIZATION

In addition to the authorization/licensing process for nuclear facilities and activities, Rostekhnadzor has implemented a process for licensing third party organizations, including manufacturing companies. These organizations provide services such as design reviews for the licensee, engineering reviews for the licensees and/or Rostekhnadzor, construction support, manufacturing of safety-related components, etc. The legal framework for this process is described in Article 14 of the “Administrative Regulation for performance of the State function of licensing the activity in the field of atomic energy use by the Federal Environmental, Industrial and Nuclear Supervision Service of Russia [Rostekhnadzor]”. In 2008, Rostekhnadzor issued licences to 171 design organizations, 224 manufacturers, and 9 engineering review organizations. A few of the licensed organizations that provide engineering review services are contracted for work by Rostekhnadzor, but the majority support licensee requests for services.

The Federal law which governs the licensing process permits a service organization (referred to as organization “A”) to contract with another service organization (referred to as organization “B”) to conduct a licence review of its documents to be submitted to Rostekhnadzor in support of a request to obtain a licence. Once organization “A” has obtained a licence from Rostekhnadzor, it may be contracted by organization “B”, which originally provided document review services for organization “A”, to review documents in support of organization “B’s” pursuit of re-licensing. Given that there are 45 licensed service organizations, this process allowance for reciprocity and can create a conflict of interest situation.

Rostekhnadzor’s current practice of licensing third party/external organizations that provide services to licensees such as engineering reviews, component manufacturing, and construction activities is contrary to the principle that the licensee has the primary responsibility for safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GSR Part 1 Requirement 5 states that <i>“Prime responsibility for safety: “The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance.”</i>
(2)	BASIS: GS-R-1 para 2.3 states that <i>“The prime responsibility for safety shall be assigned to the operator. The operator shall have the responsibility for ensuring safety in the siting, design, construction, commissioning, operation, decommissioning, close-out or closure of its facilities, including, as appropriate, rehabilitation of contaminated areas; and for activities in which radioactive materials are used, transported or handled. Organizations which generate radioactive waste shall have responsibility for the safe management of the radioactive waste that they produce. Since during the transport of radioactive material, primary reliance for safety is put on the use of approved packaging, it is the responsibility of the consignor to ensure appropriate selection and use of packaging. Compliance with the requirements imposed by the regulatory body shall not relieve the operator of its prime responsibility for safety. The operator shall demonstrate to the satisfaction of the regulatory body that this responsibility has been and will continue to be discharged.”</i>
R9	Recommendation: MNRE and Rostekhnadzor should evaluate its practice of licensing third party/external organizations that provide services and products to licensees to ensure that this approach is not contrary to the principle that the licensee’s primary responsibility to ensure safety lies with the licensee .

Time limits for completion of safety reviews

The safety review prior to granting an authorization of the nuclear facility or activity is organized by Rostekhnadzor and mainly conducted by its technical support organization (SEC NRS) in accordance with the requirements of the Administrative Regulation on Execution of the State Function of Licensing Activity in the Field of Atomic Energy Use by the Federal Environmental, Industrial and Nuclear Supervision Service (hereinafter referred to as AR) approved by Order of the MNRE No. 262 dated October 16, 2008). The time frame to complete the review process is intended to be commensurate with the potential magnitude and nature of the radiation risk associated with the facility or activity and is determined by Rostekhnadzor in accordance with Directive No. 262 dated October 16, 2008. However, while the prescribed time limit provides for a measure of regulatory predictability in terms of timely review of a safety assessment, it may not, in some instances, be sufficient for the systematic and comprehensive review of a safety assessment submitted by the applicant. For example, the maximum length of time to complete the review of the licence application for the Nuclear Power Plant is 12 months as per Article 11.1 of Directive No. 262, but it is shorter for other nuclear facilities or activities.

The scope and depth of the safety review prior to granting an authorization of the nuclear facility or activity is not performed in accordance with the stage in the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity. Therefore, the time frame prescribed for completion of the safety review may not, in some instances, be sufficient for the systematic and comprehensive review of a safety assessment submitted by the applicant.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS-R-1 para 5.7 states that <i>“Review and assessment shall be performed in accordance with the stage in the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity.”</i>
(2)	BASIS: GSR-Part 1 Requirement 26 states that <i>“Graded approach to review and assessment of a facility or an activity: states that “Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i> <i>“4.40 - The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process (initial review, subsequent reviews, reviews of changes to safety related aspects of the facility or activity, reviews of operating experience, or reviews for long term operation, life extension, decommissioning or release from regulatory control). The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i>
R10	Recommendation: The government of the Russian Federation should identify the legal procedure for removing restrictions on time limit prescribed for completion of a safety review prior to the granting of an authorization for a nuclear facility or activity. The safety review should be commensurate with the stage in the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity, in accordance with common practice in other IAEA Member States.

5.1. NUCLEAR POWER PLANTS

Rostekhnadzor verification of licensee’s staff competence

In addition to licensing the NPP operators, the Rostekhnadzor licenses senior level technical managers, plant safety engineers and plant managers. Licensing of managers is performed by the Rostekhnadzor headquarters office and consists of the administration of an exam consisting of ten randomly selected questions selected from a question bank. A score of at least 80 percent is required to successfully pass the examination. This process also includes the flexibility to add questions to the written examination to further check the competence level of a candidate. Individual licences must be renewed periodically.

The Rostekhnadzor’s process for assessing the competence of upper level technical managers and plant managers provides for a comprehensive verification of the competence level for these individuals who have a significant role in NPP safety responsibility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR-Part 1 Requirement 24, para 4.30, states that “ <i>Authorization for a facility shall include authorization of the activities taking place at the facility (e.g. operation, maintenance, engineering activities). The regulatory body shall verify, by appropriate means, the competence of individuals having responsibilities for the safety of authorized facilities and activities.</i> ”
G5	Good Practice: Rostekhnadzor’s approach to assessing the competence of senior technical and plant managers is a good practice.

5.2. RESEARCH REACTORS

As a result of the answers to the self-assessment questionnaire on NS-R-4, as well as from interviews with Rostekhnadzor personnel responsible for supervision of nuclear research facilities, it was clear that there are no requirements for organizational structures or responsibilities of key personnel to be part of the operational limits and conditions of a nuclear research facility. Consequently, the regulatory body cannot effectively control the organization structure and key position responsibilities in a nuclear research facility. Although a document with such content, called “Qualification Handbook” was compiled relevant to nuclear power plants, no similar set of requirements exists for research reactors.

Organizational structure of and key personnel responsibilities in research reactors are defined with no formal possibility of the regulatory body to control them.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: NS-R-4 para 7.38 states that “ <i>The OLC shall include administrative requirements or controls concerning organizational structure and the responsibilities for key positions in the safe operation of reactor, staffing, training and retraining of facility personnel, review and audit procedures, modifications, experiments, records and reports, and required actions following a violation of an OLC....</i> ”
R11	Recommendation: MNRE should take the necessary measures to establish the qualification requirements for personnel holding key positions in the safe operation of nuclear research facilities. Rostekhnadzor should assess the training and retraining of persons holding key positions in the safe operation of nuclear research facilities and should include the necessary training in the operating licence of the facilities.

5.3. FUEL CYCLE FACILITIES

The period between licence renewals for FCFs is normally between 3 years and an unlimited period, with exceptional periods of 1 year, if appropriate. This contrasts with NPPs and research reactors, which have defined periods. The actual re-licensing period for the facility is often determined through negotiation between the licensee and the regulator. This period is based, amongst other things, on plans for potential significant modifications or assessed lifetimes of parts of the plant.

It is recognised that there needs to be flexibility in determining the licence duration, especially for older FCFs. But there is no specified and established procedure, with clear criteria, that can be used to determine this duration.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR-Part 1 Requirement 24 para 4.37 states that <i>“Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure, and shall make provision for the timely submission of applications for the renewal or amendment of an authorization.”</i>
S16	Suggestion: Rostechnadzor should consider the possibility of establishing a procedure to determine the period of licence renewal for fuel cycle facilities.

5.4. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES (FCF)

Licensing of activities with radioactive sources

Rostechnadzor has responsibility for the authorization of industrial, medical and research facilities that undertake activities with radioactive sources. Responsibility for the authorization of radiation sources that generate ionizing radiation, and do not incorporate radioactive material, belongs to another regulatory body - Federal Service for Supervision in the Sphere of Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor). Therefore, review of the authorization of industrial, medical and research facilities that use generators is out of the scope of this IRRS review.

According to article 5.3.2 of "On Federal Environmental, Industrial and Nuclear Supervision Service", approved by Ordinance of the Government of the Russian Federation No. 401 of 30.07.2004, Rostechnadzor licenses activity with radioactive sources in two ways: issuing licences for radioactive sources facilities, and issuing permits authorizing the employees of the atomic energy facilities to work in the field of atomic energy use. No notification and registration is used. Exemption levels are defined in the “Main Sanitary Rules for the Radiation Safety Assurance” OSPORB-99 (approved in 1999 by Chief State Sanitary Inspector) and Norms of Radiation Safety NRB/2009-99 (approved in 2009 by Chief State Sanitary Inspector).

The main provisions for licensing are established by "Provision on Licensing of Activity on the Field of Atomic energy Use" approved by the Decree of the Government of the Russian Federation, No. 865 of July 14, 1997. According to the “Administrative regulations for the Federal Environmental, Industrial and Nuclear Supervision Service to perform its state function as to licensing of the activity in atomic energy use” (AR) Rostechnadzor undertakes licensing of the activities in atomic energy use. These documents establish clear procedures for issuing, reissuing, amending, suspending and revoking licences.

AR establishes that Rostechnadzor implements the regulatory activity via its headquarters and the territorial bodies. Division of responsibilities for authorization is given in AR annex.

Of those 5955 radiological facilities existing at the end of 2008, 2179 enterprises and organizations are supervised. Furthermore, 514 licences for radioactive sources, and 2627 individual permissions were

granted in 2008. The total number of permissions for individuals that have responsibility for radiation safety is now more than 15,000.

The types of activities that are subject to licensing ("Provision on Licensing of Activity on the Field of Atomic energy Use") are classified in two ways :

- radioactive source management (siting, construction, operation, decommissioning), and
- radioactive material handling.

According to regulations, four stages of radioactive sources life cycle shall be licensed: siting, construction, operation and decommissioning. In practice, only licensing of operation is undertaken.

AR provides guidance to the operator of a radiological facility on the list of documents to be submitted, including the format and content of those documents. There are about 30 such documents with only few of them to be provided "if necessary". The main submissions include the safety analysis report, the quality assurance program, a copy of the sanitary epidemiological certificate, and different financial security documents (e.g. assurance). These are general requirements for all types of the source/facility and do not take into account the potential radiological hazard. The requirements for the safety analysis report are established in the regulation "Requirements for the content of the safety analysis report for radiation sources" NP-039-02.

Rostekhnadzor maintains documentation to record the basis for granting an authorization.

There are no clear criteria in the regulations regarding the licence activities that apply, and there is no guidance that covers activities where a single legal entity is authorized by one or several licences. The term of licence can also be set for any period of 3 years or more; there is no guidance on the licence period that should be established for any specific case. Staff members make case-by-case decisions on the appropriate type of licence, the number of licences that should be issued for a single legal entity, and licence period.

Recommendations for formulating licence conditions for the activities in the field of nuclear energy use (approved by Rostekhnadzor Order # 502 17.10.2008, article 2.1.3) prohibit including into the licence those conditions that are not in the regulations. This is followed in practice, and leads to the absence of facility-specific licence conditions except those that describe the facility, materials and activities for the waste facilities and radiological facilities. For example, the IRRS Review Team reviewed several licences for the operation of radiological facilities and discovered that all of them included only a description of the sources/facilities characteristics and all other requirements were taken from regulations and were not facility specific.

Authorization regulations of radioactive sources/radioactive materials management are general for all types and/or categories of the radioactive sources. No graded approach is implemented for sources with different level of radiation hazard. In order to use a graded approach staff members make case-by-case decisions not to implement some requirements that are mandatory.

The extent of the regulatory control applied for the management/use/handling/operating of radioactive sources is not commensurate with the radiation risks associated with radiological facilities and activities, in accordance with a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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| (1) | BASIS: GSR Part 1 Requirement 22 states that <i>"Stability and consistency of regulatory control "The regulatory body shall ensure that regulatory control is stable and consistent. 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</i> |
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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>prevent subjectivity in decision making by the individual staff members of the regulatory body.</i>
(2)	BASIS: GSR Part 1 Requirement 24 states that “ <i>Demonstration of safety for the authorization of facilities and activities “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.” ...para 4.33. Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.</i> ”
(3)	BASIS: GS-R-1 para 5.3 states that “ <i>Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures. The extent of the control applied shall be commensurate with the potential magnitude and nature of the hazard presented.</i> ”
(4)	BASIS: GS-R-1 para 5.4 states that “ <i>the regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization. The operator shall be required to submit or make available to the regulatory body, in accordance with agreed time-scales, all information that is specified or requested. For complex facilities (such as a nuclear power plant) authorization may be carried out in several stages , each requiring hold points, separate permits or licences. In such cases, each stage of the process shall be subject to review and assessment, with account taken of feedback from the previous stage”</i> ”
R12	Recommendation: For activities with radioactive sources, MNRE and Rostechnadzor should prepare a proposal to change the licensing requirements so that a graded approach is applied systematically, thus avoiding unnecessary administrative burdens.
S17	Suggestion: Rostechnadzor should establish and implement criteria, internal procedures and guidance on the types, number and validity of licences that are needed by applicants, and in particular should consider if licensing is needed for all or only some of the stages in the life-time of a facility where radioactive sources are handled, i.e. siting, construction, operation and decommissioning.

Export/Import of radioactive sources

Authorization of the export and import of radioactive sources is regulated by “Provisions for the control of foreign economic activity for equipment and material of dual purpose and appropriate technologies that are used for nuclear purposes”. The competent authority is Federal Service for Export and Technological Control. Confirmation from the Importing State is required when the Federal Service for Export and Technological Control authorizes single (one-time) export Category 1 and 2 radioactive sources, but confirmation is not required when a general licence is issued. When authorizing the import, no information about the Rostechnadzor licence for the use of radioactive sources by receiver is required by Federal Service for Export and Technological Control from the applicant.

Rostechnadzor has the necessary competence, experience and knowledge in the above issues. It possesses full information on the licences issued for the national users of the sources. Rostechnadzor also has information on the regulatory bodies in other countries that can provide confirmation that the State has the

appropriate technical and administrative capability, resources and regulatory structure needed to ensure that the source will be managed in a manner consistent with the provisions of this Code.

Rostekhnadzor can help to clarify all issues about authorizations for the radioactive sources use in the Russian Federation and other countries.

The current procedures for licensing the import and export of radioactive sources are not sufficient to ensure that the requirements in the Code of Conduct are fully implemented.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: GSR Part 1. Requirement 2 states that <i>“Establishment of a framework for safety The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.”</i></p> <p><i>2.5 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:(19) Provision for controls on the import and export of nuclear material and radioactive material and for their tracking within and, to the extent possible, outside national boundaries, such as tracking of the authorized export of radioactive sources.</i></p>
(2)	<p>BASIS: Code of Conduct for the safety and security of radioactive sources 23 states that <i>“Every State involved in the import or export of radioactive sources should take appropriate steps to ensure that transfers are undertaken in a manner consistent with the provisions of the Code and that transfers of radioactive sources in Categories 1 and 2 of Annex 1 of this Code take place only with the prior notification by the exporting State and, as appropriate, consent by the importing State in accordance with their respective laws and regulations.”</i></p>
(3)	<p>BASIS: Code of Conduct for the safety and security of radioactive sources 24 states that <i>“Every State intending to authorize the import of radioactive sources in Categories 1 and 2 of Annex 1 to this Code should consent to their import only if the recipient is authorized to receive and possess the source under its national law and the State has the appropriate technical and administrative capability, resources and regulatory structure needed to ensure that the source will be managed in a manner consistent with the provisions of this Code.”</i></p>
(4)	<p>BASIS: Code of Conduct for the safety and security of radioactive sources 25 states that <i>“Every State intending to authorize the export of radioactive sources in Categories 1 and 2 of Annex 1 to this Code should consent to its export only if it can satisfy itself, insofar as practicable, that the receiving State has authorized the recipient to receive and possess the source and has the appropriate technical and administrative capability, resources and regulatory structure needed to ensure that the source will be managed in a manner consistent with the provisions of this Code.”</i></p>
S18	<p>Suggestion: MNRE and Rostekhnadzor should establish formal cooperation and exchange of information with the Federal Service for Export and Technological Control to provide for full and effective implementation of the export and import provisions of the Code of Conduct on the Safety and Security of Radioactive Sources.</p>

5.5. WASTE FACILITIES

Limits, conditions and control

The IRRS Review Team had the opportunity to review one example of an issued licence for a currently recognized “storage” (disposal) installation. The IRRS Review Team observed that, in the licence, there was no indication of the activity or volume, or any other limits for the storage of radioactive waste or

disused sealed sources in each of the authorized storage facilities. This is contrary to national standards currently in force.

NP-020-2000 on Collection, Treatment, Storage and Conditioning of Solid Radioactive Waste (para 6.2) establishes that “Engineering and organizational measures for safe solid radioactive waste (SRW) storage shall be anticipated in the design of nuclear installations, radioactive sources, storage/disposal facilities and acceptable volume of SRW, radionuclide content, activity level and storage period shall be established and justified”.

NP-069-06 on Near-Surface Disposal of Radioactive Waste (para. 4.7) establishes “The predictive calculations for the safety assessment of the RW disposal system shall serve as the basis for the NS RWDF design justification of: a composition of the system of barriers and their characteristics; a RW radionuclide composition; permissible NS RWDF averaged specific activity of radionuclides in RW disposal cells (RW packaging); and permissible NS RWDF averaged specific activity of alpha emitters (uranium, transuranic alpha emitters etc.) having a half-life of more than 5 years in RW disposal cells (RW packaging)”.

The IRRS Review Team observed that in some cases Rostekhnadzor did not indicate, even where there was a requirement to do so, limits and conditions important for safety in the granted authorizations for old operating radioactive waste storage/disposal facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: WS-R-1 para 5.2 states that “ <i>Authorized limits shall be established, as necessary, on radionuclide inventories and/or concentrations in individual waste packages and in the repository as a whole. The authorized limits shall be determined by means of appropriate safety assessment methods</i> ”.
(2)	BASIS: GS R Part I Requirement 24 para 4.31 states that “ <i>In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party’s subsequent activities.</i> ”
S19	Suggestion: Rostekhnadzor should include in all licences for operation of radioactive waste management facilities the waste activity and volume limits for the facility and other limits, conditions and controls needed for the safe operation of the facility.

Control of Discharges

Environmental protection and discharges, i.e. releases of radionuclides into the environment, are currently not fully regulated. Previously, Rostekhnadzor (i.e. Environment Supervision Service their ecological expertise department) had responsibility for establishing the limits for radioactive discharges into the environment for each radioactive or nuclear facility.

Rospotrebnadzor and FMBA developed the new NRB-99/2009, the BSS for Russia. That document gives the basis for discharge limits for each particular radionuclide. However, after Rostekhnadzor became part of the Ministry of Natural Resources and Environment, that function disappeared. Currently, there is no institution authorizing and controlling the establishment of the discharge limits. Therefore, during last two years radioactive and nuclear facilities operate according to previously defined limits. The IRRS Review Team was informed that if there is an application for a new licence (new facility, upgrade the old one etc.) there is no legal entity in Russia to set the new limits. The Ministry of Natural Resources and Environment is now considering the option to return this responsibility to Rostekhnadzor. Control of radioactive discharges is performed in the facility by regional branches of Rostekhnadzor and Rosprirodnadzor responsible for environment supervision.

Safety standards for control of radioactive discharges are established by FMBA. Currently, there is no process to assess any proposed discharge limits from the operator, based on the safety standards. The practical control of discharges is performed by local branches of Rostekhnadzor and Rosprirodnadzor.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: Basic Safety Standard para III.3. states that <i>“Registrants and licensees shall be responsible for ensuring that the optimization process for measures to control the discharge of radioactive substances from a source to the environment is subject to dose constraints established or approved by the Regulatory Authority” ...</i>
(2)	BASIS: GS R Part 5 Requirement 8 para 4.9 states that <i>“The authorized discharge of effluent and clearance of materials from regulatory control, after some appropriate processing and/or a sufficiently long period of storage, together with reuse and recycling of material, can be effective in reducing the amount of radioactive waste that needs further processing or storage. The operator has to ensure that these management options, if implemented, are in compliance with the conditions and criteria established in regulations or by the regulatory body” ...</i>
R13	Recommendation: MNRE should clarify the body that will regulate and control discharges and releases and should establish limits for the discharges and releases of radioactive substances from each nuclear or radiation facility and activity.

5.6. TRANSPORT

Due to the defined scope of the mission, only the activities and responsibilities of MNRE and Rostekhnadzor in the field of safe transport of radioactive materials were reviewed.

Transport is one of the activities in the field of the use of atomic energy (article 4 of the Federal Law ‘On the Use of Atomic Energy’, No. 170-FZ, November 21, 1995. Licensing of activities in the field of use of nuclear materials (NM) and radioactive substances (RS) during their transportation is realized in accordance with Articles 26 and 45 of that same law. The licensing procedures are defined by the Provision on Licensing of Activities in the Field of Use of Atomic Energy, approved by the Decree of the Government of Russian Federation No. 865.

According to Decree of the Government of RF, No. 401, July 30, 2004, the regulatory body in charge of the authorization is Rostekhnadzor. The first transport licence to an applicant is given for 3 years. All renewals are then granted normally for 5 years. The licence for transport of nuclear material (NM) is given by the headquarter of Rostekhnadzor, the licences for the other radioactive substances (RS) are granted by the regional offices.

6. REVIEW & ASSESSMENT

The term of the operating licence of Nuclear Power Plants is typically 10 years. For the purpose of re-licensing, safety analysis have to be conducted by the operating organization in accordance with the legislation. The scope of supporting documents is specified in Article 11 of Administrative Regulation for performance of the State function of licensing the activity in the field of atomic energy use by the Federal Environmental, Industrial and Nuclear Supervision Service of Russia. The application for a licensing renewal includes among others the following documents: safety analysis report (NP006-98; NP 018-05 and for life extension of existing operating plants in PB-001-05), the quality assurance programme for operation, a level 1 and a level 2 probabilistic safety analysis (PSA), the emergency procedure, information on training and qualification of NPP personal. The safety analysis report is generally based on the technical standards and codes used in support of the initial licence application.

Rostekhnadzor performs the review within one year as stipulated in Article 11.1 of Directive No. 262. The regulatory review may, to some extent, be based on state-of-art technical standards and codes. The resultant safety improvements and the schedule for their implementation are typically included in the operating licence as licence conditions. However, if the schedule is not specified, the operating organization may propose the time required for implementation of the safety improvements requested by Rostekhnadzor (irrespective of the duration of the licence). Rostekhnadzor considers this review process to be equivalent to the Periodic Safety Review (PSR) because of the large scope of documentation required to be submitted every 10 years for regulatory review in support re-licensing. However, for an anticipated long-term licence (i.e., beyond 10 years), this requirement may not be proper to ensure sufficient periodicity of the safety review required to demonstrate an adequate level of safety of operating facilities, as this is the practice in most of member state countries.

There is currently no legislative requirement for PSR to be conducted for other facilities such as research reactors and fuel cycle facilities. For these facilities, the licence renewal periods may vary and may not provide for an opportunity to undertake a systematic and comprehensive review in the same way as that for the 10-year licence review for NPPs, where the review and assessment can provide the equivalent of a periodic safety review, as discussed above. In general, the scope and periodicity of the safety assessment review should be determined using a graded approach commensurate with the potential magnitude and nature of the hazard associated with the particular facility rather than with the licence renewal periods. In the latter case, a provision in the licensing process is required to ensure that the resultant safety improvements be legally enforceable.

Minprirody of Russia and Rostekhnadzor have recently proposed a new legislation aimed at revising the licensing process for nuclear power plants through introducing PSR and through increasing the term of the operating licence.

Currently, specific safety analysis have to be conducted for the licence renewal process for major nuclear facilities, including Nuclear Power Plants, Research Reactors and Fuel Cycle Facilities. It is also not clear how the scope and periodicity of these analysis are determined to demonstrate an adequate level of safety of operating nuclear facilities, and how the findings are assessed and enforced to ensure that their level of safety corresponds to that in other Member State countries.

There is no legal requirement for a systematic and comprehensive re-assessment of safety of major nuclear facilities through their operational lifetime, with consideration given to the potential magnitude of hazard associated with operation of these facilities (the magnitude of hazard of the particular facility may vary, depending on the facility's type and size).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<p>BASIS: GSR Part 1 Requirement 24 states that “<i>Demonstration of safety for the authorization of facilities and activities. 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.</i>”</p>
(2)	<p>BASIS: GS-R-1 para 5.9 states that “<i>A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator’s technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator, to satisfy itself that:</i></p> <p style="margin-left: 20px;"><i>(1) the available information demonstrates the safety of the facility or proposed activity;</i></p> <p style="margin-left: 20px;"><i>(2) the information contained in the operator’s submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements; and</i></p> <p style="margin-left: 20px;"><i>(3) the technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety.</i>”</p>
(3)	<p>BASIS: GS-R-1 para 5.10 states that “<i>The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout. Additional requirements for the review and assessment of a nuclear power plant are given in the Appendix.</i>”</p>
(4)	<p>BASIS: NS-G-2.10 para 2.3 states that “<i>PSRs are considered an effective way to obtain an overall view of actual plant safety, to determine reasonable and practical modifications that should be made in order to maintain a high level of safety and to improve the safety of older nuclear power plants to a level approaching that of modern plants. In this connection, it is useful to identify any lifetime limiting features of the plant in order to help evaluate whether a proposed modification is worthwhile.</i>”</p>
(5)	<p>BASIS: NS-G-2.10 para 2.4 states that “<i>On the basis of experience, the first PSR should be undertaken about ten years after the start of plant operation and subsequent PSRs every ten years until the end of operation. Within a period of ten years, the following developments would be expected: a likelihood of significant changes in safety standards, technology and underlying scientific knowledge and analytical techniques; a need for the evaluation of the cumulative effects of plant modifications and ageing; and a possibility of significant changes in the staffing and management structures of both the plant operating organization and the regulatory body.</i>”</p>
R14	<p>Recommendation: The Government of the Russian Federation should establish legal provisions to require the conduct by the operating organization of periodic safety reviews throughout the operational lifetime of major nuclear facilities, including nuclear power plants, research reactors and fuel cycle facilities, in accordance with the IAEA Safety Standards. The systematic safety re-assessment should be performed with a sufficient periodicity to demonstrate an adequate level of safety at the facility, using a graded approach with account taken of the potential magnitude and nature of the hazard associated with the particular facility. The resulting safety improvements should be legally enforceable.</p>

The General Regulations on Ensuring Safety of Nuclear Power Plants, OPB-88/97 NP-001-97 (PNAE G-01 011-97) include requirements regarding the role of safety culture in the selection and personnel of organizations engaged in siting, construction, operation and decommissioning of NPPs, design, engineering and manufacturing of their systems.

The regulatory body has not yet developed and implemented a programme for the regulatory oversight of licensees' safety culture.

The lack of a regulatory programme for the oversight of licensees' safety culture does not allow the regulatory body to assess, in a systematic way, the status of implementation and progress made by the nuclear facilities in fostering and implementing a strong safety culture.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: GSR Part 1 Requirement 25 states that <i>“Review and assessment of information relevant to safety</i> <i>(4.44) Any proposed modification that might significantly affect the safety of a facility or activity shall be subject to a review and assessment by the regulatory body.</i> <i>(4.45) In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as:</i></p> <ul style="list-style-type: none"> – <i>The applicable management system;</i>
(2)	<p>BASIS: GS-R-1 para 5.9 states that <i>“A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator’s technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria.</i></p>
(3)	<p>BASIS: GS-R-1 para 5.10 states that <i>“The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout. Additional requirements for the review and assessment of a nuclear power plant are given in the Appendix.”</i></p>
S20	<p>Suggestion: Rostechnadzor should ensure effective oversight of licensee safety culture, including the development and implementation of a method to systematically assess indicators addressing safety culture.</p>

Integrated safety assessment approach

Rostechnadzor has access to several items of information relating to licensee safety performance. Examples include inspection reports, enforcement actions issued by Rostechnadzor, reports from the licensee on the results of its event investigations, and the annual report submitted to Rostechnadzor by the licensee that describes the current operational safety status of each unit. The licensee annual report contains a variety of information such as number of equipment failures per unit, types of effluent releases, amount of solid/liquid radioactive waste, number of safety-related modifications installed, completed maintenance activities, etc. Rostechnadzor uses these documents to conduct an integrated assessment of licensee safety performance and provides the results in quarterly summary reports and an annual report. More specifically, Rostechnadzor’s annual report contains a summary of regulatory activities, i.e., number of inspections conducted, licensing and enforcement actions, and summaries of events, for all nuclear facilities. In communicating the results of its integrated safety assessment activities to the licensee, Rostechnadzor issues letters to the licensee identifying problems/concerns based on equipment failure trending results, evaluations of equipment material condition, etc. The annual report is provided to the

licensee as well as placed on Rostechnadzor’s website. The assessment process described above is not prescribed in any formal procedure.

While it appears that Rostechnadzor does conduct some type of integrated safety assessment, this process is not governed by any procedure to ensure consistency in implementation of the process. The annual report produced by Rostechnadzor for all nuclear facilities is mostly a summary of Rostechnadzor activities and licensee events, and as such, it is not a document that communicates the results of an integrated assessment of licence safety performance conducted by Rostechnadzor. Rostechnadzor relies primarily on its quarterly summary reports and letters to the licensee as the means of communicating its integrated safety assessment results.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: GSR Part 1 Requirement 26 para 4.46, states that <i>“For an integrated safety assessment, the regulatory body first shall organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i></p>
R15	<p>Recommendation: Rostechnadzor should formalize its process via procedure for conducting a periodic integrated assessment of licensee safety performance, including definition of the scope, specification of how the assessment should be conducted, the manner of communicating the assessment results, and the use of the assessment results in formulating appropriate strategies for future regulatory oversight of the licensee.</p>

Rostechnadzor assessment of modifications

If the licensee plans to modify any system or component that may affect safety, the licensee submits the modification to Rostechnadzor for approval. If the modification requires a change to any licence condition, then it is assessed by Rostechnadzor’s headquarters staff. However, if there is no change to any licence condition then the modification is assessed by the resident (site) inspector.

Given that all modifications to safety-related structures, systems, and components are submitted to Rostechnadzor for approval, it is important that Rostechnadzor’s review of the modification is sufficient relative to the modification’s safety significance. The categorisation based just on the change to licence condition does not adequately provide this.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: GSR-Part 1 Requirement 26 para 4.44 states that <i>“Any proposed modification that might significantly affect the safety of a facility or activity shall be subject to a review and assessment by the regulatory body.”</i></p>
R16	<p>Recommendation: Rostechnadzor should develop a safety classification system for plant modifications, including those that do not require changes to licence conditions, in order to assist in determining the degree of regulatory assessment required before approving the modification.</p>

6.1. NUCLEAR POWER PLANTS

Gosatomnadzor of Russia (today Rostechnadzor) issued in 1999 a policy statement entitled “Application of Probabilistic Safety Analysis for Operating Units of Nuclear Power Plants”. The document presents the potential scope of PSA, outlines PSA as a tool to define risk-related safety goals and describes the expectation of Gosatomnadzor on the future development of PSA. Furthermore, the following risk-related safety goals for design and operation were included in the regulatory document “General Provisions of NPP Units” (OPB-88/97):

- it is necessary to aspire that PSA estimated value of total probability of severe accidents will be less than $1E-5$ per reactor year;
- to exclude the necessity of evacuation of the population beyond the planned protective measures area established in accordance with regulatory requirements to NPP siting it is necessary to aspire that PSA estimated value of probability of extreme accidents release will be less than $1E-7$ per reactor year.

Consequently, PSA has been used to identify specific improvements to the plant safety for potential implementation, and to assess some events and approve plant modifications identified by the licensee.

The current practice is to use PSA as an additional tool in the regulatory safety assessment. However, the role of PSA applications in regulatory framework has not been clearly defined yet. Furthermore, potential future application (e.g. identifying risk-relevant components for the aging surveillance programme) have not been investigated yet in detail.

PSA of nuclear power plants is currently used to identify specific improvements to the plant safety for potential implementation. In addition, PSA is also currently used to assess some events and approve plant modifications proposed by the licensee. However, the role of PSA is not clearly defined in order to ensure the consistency of the regulatory decision making. Furthermore, potential future PSA applications have not been investigated yet in detail.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<p>BASIS: GS-R-1 para 5.9 states that “<i>A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator’s technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator, to satisfy itself that:</i></p> <p><i>(1) the available information demonstrates the safety of the facility or proposed activity;</i></p> <p><i>(2) the information contained in the operator’s submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements; and</i></p> <p><i>(3) the technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety.”</i></p>
(2)	<p>BASIS: NS-R-1 para 5.2 states that “<i>The method for classifying the safety significance of a structure, system or component shall primarily be based on deterministic methods, complemented where appropriate by probabilistic methods and engineering judgement, with account taken of factors such as:</i></p> <p><i>(1) the safety function(s) to be performed by the item;</i></p> <p><i>(2) the consequences of failure to perform its function;</i></p> <p><i>(3) the probability that the item will be called upon to perform a safety function;</i></p> <p><i>(4) the time following a PIE at which, or the period throughout which, it will be called upon to operate.”</i></p>

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(3)	<p>BASIS: NS-R-1 para 5.73 (6) states that <i>“A probabilistic safety analysis of <u>the</u> plant shall be carried out in order: ... (6) to identify systems for which design improvements or modifications to operational procedures could reduce the probabilities of severe accidents or mitigate their consequences;</i></p>
S21	<p>Suggestion: Rostekhnadzor should update policy statement in order to:</p> <ul style="list-style-type: none"> - define the role of the PSA in integrated decision making, - ensure that the PSA is consistently used for the assessment of events and plant modifications, and - consider potential future PSA applications in accordance with NS-R-1, paras 5.2, 5.73.
S22	<p>Suggestion: Rostekhnadzor should consider supporting the implementation of the updated policy statement on the use of PSA by a pilot study for a nuclear power plant, focusing on the evaluation of events (for a specific time interval), operational limits and conditions, and the importance of correct safety classification of components</p>

6.2. RESEARCH REACTORS

The self-assessment of Rostekhnadzor has indicated that no explicit requirements exist to ensure that the results of all stages of the commissioning programme are made available for the regulatory body for review and assessment.

Safety Analysis Reports of the nuclear research facilities are reviewed with a periodicity. The SARs include also the Operational Limits and Conditions of the facilities. The reviewed SARs are not requested to be submitted to the regulatory body neither for approval, nor for inspection.

Operators of nuclear research facilities annually organize reviews of the facilities by appointing members to ad hoc committees from their staff. Results of such activities are considered by a Rostekhnadzor inspector at the nuclear research facility. Although it may be an effective way of undertaking safety reviews, such committees are not independent from the management of the operators nor do they provide a continuing support to decision-making on safety relevant issues. Similarly no support to the reactor manager is expected from such committees.

There are no explicit requirements in the administrative regulations for the results and analysis of nuclear research facility commissioning to be submitted to Rostekhnadzor.

The main documents defining the safety related features and the operational requirements of the nuclear research facilities may undergo changes without the knowledge or consent of the regulatory body.

Safety commissions independent of the operator’s management, support the operator as well as the reactor managers by advice in issues having effect on the safety of nuclear research installations.

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(1)	<p>BASIS: NS-R-4 para 7.44. states that <i>“The commissioning programme shall be submitted to the safety committee and the regulatory body and shall be subjected to an appropriate review and assessment before being implemented.”</i></p>
(2)	<p>BASIS: NS-R-4 para 7.45. states that <i>“...the results and analyses of tests directly affecting safety shall be made available to the safety committee and the regulatory body for review and approval as appropriate.”</i></p>
R17	<p>Recommendation: MNRE should establish explicit requirements to ensure that the results and analysis of all stages of the commissioning programme are submitted for review and</p>

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	assessment to Rostechnadzor.
(1)	BASIS: NS-R-4 para 2.16. states that <i>"Activities for systematic periodic assessments include, among others, periodic reviews such as self-assessment reviews and peer review to confirm that the SAR and other selected documents (such as documentation for operational limits and conditions (OLCs), maintenance and training) for the installation remain valid or, if necessary, to make improvements. In such reviews, the cumulative effects of modifications, changes to procedures, the ageing of components, the use of feedback from operating experience and technical developments need to be considered, and it is necessary to verify that selected SSCs and software comply with the design requirements."</i>
S23	Suggestion: Rostechnadzor should, as part of the licence condition, request the operators of nuclear research facilities to submit the safety analysis report for review after its <u>periodic</u> revision.
(1)	BASIS: NS-R-4 para 4.15. states that <i>"One or more reactor advisory groups or safety committees that are independent of the reactor manager shall be established to advise the operating organization on: (a) relevant aspects of the safety of the reactor and the safety of its utilization and (b) on the safety assessment of design, commissioning and operational issues."</i>
(2)	BASIS: NS-R-4 para 7.25. states that <i>"The safety committee advising the reactor manager shall provide judgements on the safety issues submitted by the reactor manager. In particular, the safety committee shall review the adequacy and safety of proposed experiments and modifications and shall provide the reactor manager with recommendations for action."</i>
R18	Recommendation: In the licence review of each research reactor, Rostechnadzor should consider the need to establish an independent safety committee supporting the reactor manager, and if appropriate, include the requirement of such a safety committee in the licence OLC.

6.3. FUEL CYCLE FACILITIES

Probabilistic Safety Analysis (PSA) provides a complementary approach to design basis analysis in the safety assessment of the design and operation of nuclear facilities. As part of licensing, the scope of documents justifying nuclear and radiation safety for NPP Unit construction and operation includes a requirement for PSA. There is no similar requirement for PSA for FCFs, even for those Category 1 facilities that have a hazard potential comparable to NPPs.

Probabilistic techniques for safety assessment of FCFs are less well-developed than for NPPs. Nevertheless probabilistic techniques, e.g. semi-probabilistic design basis analysis, are often used to assess the risk of such facilities against defined acceptance criteria. Russian licensees have performed such analyses for some FCFs, and the regulatory body is considering commissioning work from the TSO to further develop probabilistic techniques for risk assessment of FCFs.

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(1)	<p>BASIS: NS-R-5 Section 6.4 states that <i>“Within these requirements and the general framework presented in Section 2, the operating organization shall establish explicit criteria for the level of safety to be achieved. The operating organization shall set limits on the radiological consequences and associated chemical consequences for the workforce and the public of direct exposures to radiation or authorized discharges of radionuclides to the environment. These limits shall apply to the consequences of operational states and the possible consequences of accident conditions at the facility and shall be set equal to, or below, international and national standards to ensure compliance across the full range of operating conditions and throughput. For new designs, targets shall be considered that are below these limits, since it is generally more effective to incorporate enhanced safety provisions at the design stage.</i></p>
S24	<p>Suggestion: Rostekhnadzor should continue to explore how probabilistic assessment techniques can be developed and used to assess the safety of category 1 fuel cycle facilities.</p>

There is currently no requirement for the periodic safety review of FCFs. The licence renewal periods for FCFs, which may vary, do not provide for an opportunity to undertake a systematic review in the same way as that for the 10-year licence review for NPPs, where the review and assessment can provide the equivalent of a periodic safety review (see Section 5.1).

Category 1 FCFs may have a similar hazard potential to NPPs and therefore there is no reason for the degree of review and assessment for those FCFs to differ significantly from that for NPPs. Other categories of FCF have a lower hazard potential and therefore it is appropriate that the degree of review and assessment should accord with a graded approach.

6.4. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

Review and assessment of radioactive sources operation and radioactive materials handling (radioactive sources use) is an essential part of the authorization. According to the para 18.3.1.2 of AR, review and assessment are performed to make sure that the requirements of the federal regulations for safety are met. The main criteria to decide if the applicant has justified the safety of radioactive source are:

- a) conformity of the design, engineering and technical decisions with the federal codes and standards in the field of atomic energy use, qualification of employees in line with the established requirements, and availability of conditions for its maintenance at the necessary level, as well as availability and conformity with the established requirements for radioactive waste collection, storage, processing and disposal system in implementing the declared activity;
- b) the completeness of technical and organizational measures for ensuring nuclear and radiation safety in implementing the declared activity;
- c) availability of the relevant conditions for storage and arrangement of control and accounting of nuclear materials, radioactive substances, ensuring physical protection of the nuclear installation, radiation sources, storage facilities, nuclear materials and radioactive substances, action plans for protection of the employees of the atomic energy facility in the event of accident and preparedness for its fulfillment, as well as the quality assurance system and necessary engineering and technical support of the declared activity;
- d) applicant's ability to provide conditions for safe termination of the declared activity and decommissioning of the atomic energy facility, as well as the availability of relevant design documents.

For the assessment the following documents are used:

- NP-039-02. Composition and contents of the report on radiation safety at radiation hazardous facilities.
- RB-042-07. Procedure for categorizing closed radionuclide sources depending on their potential radiation hazard.
- NP-038-02. General Provisions for the Safety of Radiation Sources.

All these guidelines are general for all types of radioactive sources, and Rostekhnadzor has plans to implement a graded approach. There are no internal guides for review and assessment of radiation sources use and Rostekhnadzor has plans to establish such guides.

According to the “Administrative regulations for the Federal Environmental, Industrial and Nuclear Supervision Service to perform its state function as to licensing of the activity in atomic energy use” (AR) assessment is provided by an external expert organization. This expert organization is suggested by the applicant, or Rostekhnadzor can choose an expert organization with which it has a state contract (para. 18.3.3.7 AR). The terms of reference for expert review are prepared by Rostekhnadzor. If the expert conclusion is negative and states that safety is not assured then this would be reason for refusal to grant a licence (19.9 AR). Each expert conclusion is subject to acceptance by Rostekhnadzor by verifying that all terms of reference are covered and the conclusions are unambiguous (18.3.3.11 AR).

A general requirement for the licensee, given in the licence conditions, is to periodically supply a report on its operation. The requirements on the contents and structure of the report is established in “Requirements for the content of the report about the state of the radiation safety at the radiation hazardous objects”, RB-012-04. The regional office that issues the licence decides upon the periodicity, but in general these reports need to be submitted at least once every year. These reports are systematically analyzed and findings are fed into the inspection process.

The assessment and review of industrial, medical and research facilities and its associated activities is primarily done in connection with the licensing of the activity and as a part of the yearly review of the annual reports supplied by the licensees in accordance with the licence conditions. The information supplied in the licensing stage and the way the yearly reports are processed by the regional offices are quite sufficient for Rostekhnadzor to make conclusions on the compliance with relevant safety objectives, principles and associated criteria for safety.

6.5. WASTE FACILITIES

There is no separate safety assessment report (SAR) for some of the existing (old) waste management (WM) facilities. The depth and extent of safety assessment for older waste management facilities is limited and does not comprehensively assess doses to members of the public, in the long term, from normal and accident situations, and optimization of the waste management program. At large WM sites where several different storage facilities could exist on one site, there are no safety assessments for existing/old WM “storage/disposal” facilities. For the new or planned WM facilities, comprehensive SARs are prepared.

In the self-assessment questionnaire Rostekhnadzor answered “yes” to the question: “Does the regulatory body require that an operator of a predisposal waste management facility submits a safety assessment and implements a quality system for review and approval before being authorized to start operations?”. However, the list of documents given in the questionnaire, plus two additional ones reviewed by the IRRS Review Team (HII-058-04 and HII-020-2000), were found to be insufficient for the operator to develop a safety assessment report for some of the existing radioactive waste management facilities (see for example GSR part 5, requirements 13 – 16).

Consolidation of SARs for WM facilities and activities will help to clarify the real level and extent of the safety at waste management facilities. It is therefore recommended that the Safety Case and Safety Assessment for existing waste management facilities are revised and structured to be in line with current regulations and the safety requirements. Arrangements should be put in place to ensure that the safety case for the existing radioactive waste management facilities describes how all the safety aspects of the site, the facility design, and the managerial controls, satisfy the regulatory criteria. These should take into account the national regulations and some of the requirements of the Joint Convention on radioactive waste management, for new and existing waste management facilities.

In addition, the safety assessment report for radioactive waste management facilities has to be periodically reviewed as is recommended in the IAEA Safety Standards (GSR Part 5, Requirements 16). This is missing in the existing regulations.

The broader aspects of the safety case for waste management other than calculation of dose and risk, e.g. justification of treatment, conditioning and storage options, suitability of equipment (fitness for purpose, good engineering practice, defense in depth, compatibility of materials, robustness), appropriateness of waste forms, optimization of the waste management programme, and the approach to clearance and discharges should be particularly emphasized in the safety documentation. Also Rostekhnadzor would benefit from a well-defined requirement on management system associated with the safety case and safety assessment process. It is expected that the new Law on Radioactive Waste Management will clarify the responsibilities for the post-military wastes and facilities, and others where regulations and requirements on safety assessment and safety case are missing.

The IRRS Review Team observed that not all the requirements needed for the development of the safety assessment and safety case for all types of waste storage and disposal facilities are being developed.

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(1)	BASIS: GSR Part5 Requirement 3 states that <i>“Responsibilities of the regulatory body establishes: “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. The regulatory body shall review and assess the safety case and the environmental impact assessment for radioactive waste management facilities and activities, as prepared by the operator both prior to authorization and periodically during operation. The regulatory body shall provide for the issuing, amending, suspension or revoking of licences, subject to any necessary conditions. The regulatory body shall carry out activities to verify that the operator meets these conditions. Enforcement actions shall be taken as necessary by the regulatory body in the event of deviations from, or noncompliance with, requirements and conditions.”</i>
(2)	BASIS: GSR Part5 Para 5.2. states that <i>“It is the responsibility of the regulatory body to derive and document in a clear and unambiguous manner the criteria on which the regulatory decision making process is based. It is important that any additional guidance provided by the regulatory body takes account of the wide range of predisposal radioactive waste management facilities that may be developed and the wide range of activities that may be conducted at these facilities.</i>
R19	Recommendation: MNRE and Rostekhnadzor should develop requirements for the safety assessment and safety case for different types of radioactive waste management facility that do not yet have proper requirements. These requirements to be developed should address separately the facilities that already exist and those that will be built in the future. In implementing this recommendation, Rostekhnadzor should consider the current actual status of existing radioactive waste storage facilities intended either for interim use only, or for final

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disposal.

6.6. TRANSPORT

Like for all activities it regulates, Rostekhnadzor organizes review and assessment of transport application by engaging independent experts or expert organizations. These expert organizations have to be licensed by Rostekhnadzor to perform the review and assessment of the applications. Review of the documents submitted in the application for a licence granting the right to handle nuclear material and radioactive sources during transportation is foreseen within Article 19 of the Provision on Licensing of Activities in the Field of Use of Atomic Energy, approved by the Decree of the Government of Russian Federation No. 865, July 14, 1997.

This includes two stages which are review of the submitted documentation by experts or experts organizations and inspection of the applicant by Rostekhnadzor.

7. INSPECTION

Inspector access

While the current regulatory structure allows for unrestricted access to the nuclear facilities by Rostekhnadzor’s inspectors, Federal law No. 294, which pertains to the legal rights of persons and individual entrepreneurs subject to inspection by governmental organizations, contains limitations on the frequency and duration of Rostekhnadzor inspection activities, i.e., in case of comprehensive inspections 3 years and 20 days, respectively, while the frequency of targeted inspections is annually. This law, if enacted as currently written, would preclude regulatory body inspectors from having access to the nuclear facilities at any time, thus significantly impacting the effectiveness of Rostekhnadzor’s inspection function. Another requirement of recent regulations is that the annual inspection plan of the regulatory body is subject to consent by the General Prosecutor Office.

Administrative limitations on the frequency of nuclear facility safety inspections by Rostekhnadzor are contrary to the principle of ensuring nuclear safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: GSR Part 1 Requirement 29 para 4.52 states that <i>“Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach.”</i></p>
(2)	<p>BASIS: GS-R-1 para 5.14. states that <i>”The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity.”</i></p>
R20	<p>Recommendation: The government of the Russian Federation should pursue all means to make changes in Federal law No. 294 that would establish the necessary conditions for supervision of nuclear and radiation safety in accordance with the IAEA safety standards. In the same connection other currently existing limitations on independent inspection activities should also be eliminated.</p>

Inspector objectivity

The inspection program for both nuclear power plants (NPPs) and fuel cycle facilities (FCFs) consists of comprehensive, targeted, and site (resident) inspections of the operating organization (OO). The periodicity for comprehensive inspections is between three to five years, which is a function of licensee safety performance for NPPs and the significance of the radiological hazard for FCFs. The comprehensive inspections are led by the headquarters office and staffed by inspectors from headquarters, the regional offices, and the sites. The targeted inspections focus on a specific area such as facility modifications, physical protection, and training/qualification. Typically, the targeted inspections are staffed by inspectors from the regional offices and sites. Inclusion of inspectors from other sites and the regional offices on the comprehensive and targeted inspections does provide for information sharing between inspectors and awareness of issues at other NPPs and FCFs. In addition, the results of the comprehensive inspection are compared to the results over time of the inspections conducted by the resident inspectors to provide an indicator of resident inspector performance and objectivity.

In addition, the headquarters office of the regulatory body (RB) conducts comprehensive audits of the regional offices on a five-year frequency. This audit includes an evaluation of the regulatory performance of the resident inspectors. The resident inspector’s supervisor, who is based in the regional office, visits the NPP on average once a quarter and interacts with the resident inspectors assigned to the NPP.

Regarding time on site by the resident inspectors, many resident inspectors have been assigned to the same site for a number of years. For example, in the case of the Kalinin NPP, one of the resident inspectors has been assigned to the site for 34 years.

Resident inspectors are typically assigned, at the same site for many years. Although there are targeted inspections involving colleagues from other regional offices and sites, there is no specific program for routine supervisory visits to the NPPs or FCFs to interact with the resident inspectors. Furthermore, comprehensive audits of the regional office and comprehensive inspections of the operating organizations (OO) can be conducted as infrequently as every five years. Therefore, the potential exists for the regulatory body not to be aware of a resident inspector’s potential loss of objectivity.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GS R Part 1 Requirement 17, para 4.8 states that <i>“To maintain the effective independence of the regulatory body, special consideration shall be given when new staff members are recruited from authorized parties, and the independence of the regulatory body, regulatory aspects and safety considerations shall be emphasized in their training. The regulatory body shall ensure that its staff operate professionally and within its remit in relation to safety.”</i>
S25	Suggestion: Rostechnadzor should consider developing a programme or process to ensure resident inspector objectivity for continuing unbiased and fully independent assessment of the licensee’s safety performance.

Inspection approach

The structure of the inspection program for NPPs and FCFs is defined by the regulatory body. The specific program content is prescribed by detailed inspection procedures that are primarily focused on documentation reviews and process controls for the various activities. The regulatory bodies approach to inspection, in large part, does not include an evaluation of the adequacy of the operating organization procedures and management control systems for safety-related activities. It also includes limited observations of operators and workers for the purpose of developing an assessment of how effectively the OO is managing, controlling, and executing safety-related activities such as testing, maintenance, equipment configuration changes, power manipulations, etc.

In addition, for a number of safety-related activities, the inspection procedures require the regulatory body to approve or confirm completion of specific actions/steps, in essence, providing a quality control function. For example, the resident inspectors approve via their signature, equipment/system testing protocols and restart readiness following a refueling outage.

The Rostechnadzor approach to inspection is more procedure/document compliance-based versus performance-based. In addition, for various safety-related activities, the Rostechnadzor is exercising a quality control function rather than this being solely the responsibility of the OO. The Rostechnadzor recognizes that quality control should not be a role of the resident (site) inspectors and is planning to revise the administrative regulations defining the inspection process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<p>BASIS: GS-R-1 para 5.13 states that <i>“The main purposes of regulatory inspection and enforcement are to ensure that:</i></p> <p><i>(1) facilities, equipment and work performance meet all necessary requirements;</i></p> <p><i>(2) relevant documents and instructions are valid and are being complied with;</i></p> <p><i>(3) persons employed by the operator (including contractors) possess the necessary competence for the effective performance of their functions;</i></p> <p><i>(4) deficiencies and deviations are identified and are corrected or justified without undue delay;</i></p> <p><i>(5) any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate; and</i></p> <p><i>(6) the operator is managing safety in a proper manner.</i></p> <p><i>Regulatory inspections shall not diminish the operator’s prime responsibility for safety or substitute for the control, supervision, and verification activities that the operator must carry out.”</i></p>
R21	<p>Recommendation: Rostekhnadzor should thoroughly evaluate its approach to the inspection function to determine if the current approach is creating a situation where Rostekhnadzor inspections are providing a substitute for quality control measures, which are the primary responsibility of the operating organization. The Rostekhnadzor should initiate changes to its inspection programme procedures as appropriate.</p>
R22	<p>Recommendation: Rostekhnadzor should evaluate its approach to the inspection function and determine if it should include more observation and assessment of practical activities conducted by the licensee instead of mostly focusing on document/procedure compliance, This would increase the efficiency and effectiveness of the inspection programme.</p>

WASTE

The IRRS Review Team was informed that there are two types of inspections – planned and unplanned. Planned inspections can be comprehensive, when inspectors from other areas are involved and the whole facility is checked, or targeted where certain components or parts of the plants are inspected in detail. Planned inspections have to be announced at least two weeks in advance. Unplanned inspections are called operative, when inspector(s) arrive at the facility without previous announcement. In addition, the Headquarters can inspect their regional branches to ensure that they undertake appropriate inspections and to confirm the proper status on the site, i.e. to check if the local inspector’s judgments are independent and unbiased. There is a very good and systematic approach for annual planning of the comprehensive and targeted inspections. However, this gives limited scope to provide a longer-term strategic picture of the control over the nuclear facilities and activities.

The IRRS Review Team participated in a planned inspection to Moscow Regional Radon Facility. The regional inspectors organized and prepared the inspection in a proper manner. They demonstrated knowledge, conducted the inspection, and reviewed the requested documentation. The site inspection was well performed. The final report to the operator was precise and well presented. However, the IRRS Review Team noticed that the inspectors did not have their own measurement equipment to control dose rate and contamination in the visited areas.

The inspections were well planned and performed in accordance with the established procedures. Nevertheless, it could be improved by having more strategic planning of the inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GSR-Part 1 Requirement 29: para 4.50 states that “ <i>The regulatory body shall develop and implement a programme of inspection of facilities and activities to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach.</i> ”
(2)	BASIS: GS-R-1 para 5.14 states that “ <i>the regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity.</i> ”
S26	Suggestion: Rostekhnadzor should also consider planning for inspections a period longer than one year to provide a comprehensive view over all the issues to be reviewed and progress made by the inspected facilities in the medium and long term.

Comprehensive inspections

The system of regulatory inspections, in particular comprehensive inspections, has undergone changes since the formation of Rostekhnadzor. From 2007 up until June 2008, some comprehensive inspections of the operator’s activities were held in conjunction with an overall inspection of the regional Rostekhnadzor office responsible for the supervision of the inspected operating organization.

Combination of internal and external comprehensive inspections by Rostekhnadzor makes the inspection process unnecessarily complicated, while serving partially conflicting purposes and thus reducing the effectiveness of the process. Furthermore, this practice limits the participation of the resident inspectors in the planning of comprehensive inspections. While Rostekhnadzor has discontinued this practice, it has not formalized its new approach in a procedure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: NS-R-4 para 3.15. states that “ <i>the regulatory body shall establish a planned and systematic inspection programme. The scope of this programme and the frequency of inspections shall be commensurate with the potential hazard posed by the research reactor</i> ”
(2)	BASIS: NS-R-4 para 4.1. states that “ <i>the operating organization shall have the prime responsibility for the safety of the research reactor over its lifetime, from the beginning of the project for site evaluation, design and construction, through to commissioning, operation, utilization, modification and decommissioning. In order to ensure rigour and thoroughness at all levels of the staff in the achievement and maintenance of safety, the operating organization shall:</i> <i>(a) Establish and implement safety policies and ensure that safety matters are given the highest priority;</i> <i>(b) Clearly define responsibilities and accountabilities with corresponding lines of authority and communication;</i> <i>(c) Ensure that it has sufficient staff with appropriate education and training at all levels;</i> <i>(d) Develop and strictly adhere to sound procedures for all activities that may affect safety, ensuring that managers and supervisors promote and support good safety practices while correcting poor safety practices;</i> <i>(e) Review, monitor and audit all safety related matters on a regular basis, implementing</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p><i>appropriate corrective actions where necessary;</i></p> <p><i>(f) Be committed to safety culture on the basis of a statement of safety policy and safety objectives which is prepared and disseminated and is understood by all staff. The functions and responsibilities of the operating organization for ensuring safety in each of the above stages are presented in paras 2.11–2.23 as well as here in Section 4. Specific requirements are established in Section 5 (see 25 paras 5.2, 5.40), Section 6 (see para. 6.4) and Section 7. Requirements for preparing for decommissioning are established in Section 8 (see para. 8.7).</i></p>
(3)	<p>BASIS: GS-G-1.3 para 4.8. states that <i>"Arrangements should be made to ensure that all relevant staff of the regulatory body can fully contribute to the planning of inspections and in particular, if the offices of the regulatory body are distributed over a wide area, that resident inspectors are involved in the planning process. This will ensure the best use of the skills and knowledge of its staff"</i></p>
S27	<p>Suggestion: Rostechnadzor should consider documenting its new practice with respect to comprehensive inspections, so that inspection of licensees or operating organizations are separate from, and independent of, any internal audit of regional offices.</p>

7.1. FUEL CYCLE FACILITIES

The regulatory body undertakes comprehensive inspections with membership from the HQ, the regional office, another regional office, and the site inspectors of the appropriate facility. The membership consists of inspectors and specialists with experience of FCFs, but does not include team members that inspect other types of nuclear facilities.

Experienced nuclear and radiation safety inspectors with NPP experience may identify issues and share knowledge and experience related to NPPs that is relevant to FCF safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<p>BASIS: GS-G-1.3 para 3.8 states that <i>"Team inspections, which may be multidisciplinary, provide an in-depth, independent and balanced assessment of the operator's performance. This type of inspection may vary in both scope and complexity. Team inspections are of particular value once safety problems have been identified, since normal inspections cover only small samples of the operator's activities in any particular area. Inspections of this type will identify underlying causes of problems in order to determine whether a safety concern represents isolated cases or may signify a broader, more serious problem."</i></p>
(2)	<p>BASIS: GS-G-1.3 para 4.1 states that <i>"To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail. The guidelines should be followed to ensure a systematic and consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise. Appropriate information and guidance should be provided to the inspectors and each inspector should be given adequate training in following this guidance."</i></p>
S28	<p>Suggestion: Rostechnadzor should consider whether there is benefit in including in its comprehensive inspection teams some inspectors with detailed regulatory experience of other types of nuclear facilities to provide fresh insights and transfer good practice.</p>

7.2. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

One of the tasks for the Rostechnadzor HQ is to support and guide the regional offices so that inspections of a certain type of activity are focused on the relevant aspects of that activity and performed in a harmonized way throughout the regions.

One way the HQ does this is by issuing both general and specific instructions on inspections. In the instructions for comprehensive inspections, the HQ has compiled a list of items reflecting all potential issues that has to be checked and which can be generally applied to all activities (RD-07-13-2001, Typical radiation safety targeted inspection program). Aside from this, Rostechnadzor HQ has also issued 4 instructions for inspection of certain specific types of activities, namely:

1. Methodological instruction for the supervision of assurance of radiation safety for the facilities that conduct geophysical research with the use of radionuclide sources, RD-07-16-2003
2. Methodological instruction for the supervision of assurance of radiation safety for the operation of gauges, RD-07-11-2001
3. Methodological instruction for the supervision of assurance of radiation safety for the operation of teletherapy installations, RD-07-15-2002
4. Methodological instruction for the supervision of assurance of radiation safety for the operation of devices of non-destructive control that includes radioactive substances (gamma radiography devices), RD-07-10-2001

For other inspections, which are not of a comprehensive nature or aimed at the above stated activities, it is up to the head of the regional office to issue guidance or approval of the issues to inspect, taking into account a graded approach. One way the HQ can support and harmonize this decision process is by issuing the guidelines or methodological instructions as mentioned above. This is a good practice that the HQ has initiated and it should be encouraged to include more specific activities.

Once every year there is a meeting between the heads and deputies of the regions with representatives from the Rostechnadzor HQ. This meeting is arranged by the regions on a rolling schedule and all inspectors that belong to the host region can, if possible, attend the meeting. These meetings serve as a good way to discuss common issues.

Rostechnadzor HQ has issued guidance to ensure that inspections are carried out in a harmonized way, taking into account a graded approach, but not for all activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part 1; Requirement 27 states that <i>“Inspection of facilities and activities: The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization”</i>
(2)	BASIS: GSR Part 1; Requirement 29 states that <i>“Graded approach to inspections of facilities and activities: Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach”</i>
S29	Suggestion: Rostechnadzor headquarters should complement and broaden its instructions on inspections to support full compliance assurance by a graded approach throughout the regions.

7.3. TRANSPORT

As for all activities, realization of inspections for transportation of Nuclear Material and Radioactive sources is foreseen within Article 25 of Federal Law ‘On the Use of Atomic Energy’, No. 170-FZ, November 21, 1995.

In accordance with item 5.3.1 of the Provision on the Federal Environmental, Industrial and Nuclear Supervision Service of Russia (Rostekhnadzor), approved by the Decree of the Government of the Russian Federation No. 401, July 30, 2004, Rostekhnadzor checks compliance with requirements of ‘The Safety Regulations For Transport of Radioactive Material’ NP-053-04 through organization of inspections of consignor, carrier and consignee of NM and RS. These inspections are performed by inspectors of regional offices of Rostekhnadzor (there are seven regional offices in the RF). As mentioned above, inspections are also performed in case of application for a licence granting the right for the handling of NM and RS during their transportation in compliance with Article 19 of The Provision on Licensing of Activities in the Field of Use of Atomic Energy, approved by the Decree of the Government of the Russian Federation No. 865, July 14, 1997.

In the field of the transport of radioactive material, three types of inspections, namely comprehensive inspections, target inspections and routine inspections are performed by Rostekhnadzor. The Headquarters of Rostekhnadzor (Department on regulation of safety of nuclear fuel cycle facilities) organizes about five comprehensive inspections per year containing also the activity “Transportation”. Target inspections are usually performed by the regional offices and sometimes also by the headquarters. Routine inspections are conducted by regional offices.

The suggestion under 7.2 also applies for transport inspections.

8. ENFORCEMENT

The regulations presently in force with respect to the safe use of nuclear energy, specifically, Article 76 of RD-03-43-98, explicitly require that enforcement actions be commensurate in character and effect with the severity and frequency of the non-compliances. Fines that may be imposed by Rostekhnadzor on the licensee have been substantially limited in sum and the ability of Rostekhnadzor to direct the suspension of nuclear facility operations or nuclear safety activities licence is limited in time

The current regulatory framework is such that it may limit the ability of Rostekhnadzor to take effective enforcement actions for significant violations of regulatory requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	<p>BASIS: GSR Part 1 para 4.54. states that <i>”The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach”</i>,</p> <p>4.55. <i>”Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization.”</i></p>
(2)	<p>BASIS: GS-R-1 para 5.18. states that <i>”Enforcement actions are designed to respond to non-compliance with specified conditions and requirements. The action shall be commensurate with the seriousness of the non-compliance. Thus there are different enforcement actions, from written warnings to penalties and, ultimately, withdrawal of an authorization.”</i></p>
S30	<p>Suggestion: MNRE should initiate changes to the respective legislation in order to ensure that Rostekhnadzor has the ability to issue to major operating organizations appropriate enforcement actions that are commensurate with the seriousness of the non-compliances.</p>
S31	<p>Suggestion: Rostekhnadzor should clarify the actual legal background of enforcement, and should make it clear to every member of the regulatory body having any role in enforcement activities.</p>

Licensee accountability for violations

Rostekhnadzor’s primary enforcement tools, for example financial penalties or removal of permits, concentrate on individuals rather than licensees. For example, typically in response to repeat violations resulting from licensee failure to take appropriate measures to prevent recurrence of the associated non-compliance, Rostekhnadzor considers suspension of the licence (permit) for the individual(s) most directly involved in the non-compliant activity or fines to the individual(s).

Rostekhnadzor’s practice of concentrating its enforcement actions on individuals does not provide for holding the licensee accountable for remedying non-compliances. Notwithstanding that there are some situations where individual enforcement action is appropriate, such as deliberate violations of regulatory requirements, Rostekhnadzor’s current approach to enforcement does not align with the fundamental concept that the licensee is ultimately accountable for safety performance. As such, the licensee is expected to take appropriate actions to prevent the recurrence of violations, which includes providing its employees with the tools necessary to be successful, e.g. remedial training, proper procedures, etc. This approach also discourages open communications to management regarding human performance errors, and the promotion of a healthy safety culture.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GSR Part 1, Requirement 31 para 4.57 states that <i>“The authorized party shall be held accountable for remedying non-compliances, for performing a thorough investigation in accordance with an agreed timetable and for taking all the necessary measures to prevent recurrence of the non-compliances.”</i>
S32	Suggestion: Rostekhnadzor management should emphasize the use of sanctions on the licensee rather than on individuals as a means of holding the licensee accountable for preventing recurrence of non-compliances. This management policy should be clearly communicated to Rostekhnadzor inspection staff.

8.1. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

An inspector that identifies a violation or a shortcoming shall classify the violation and describe it in the inspection report. The report shall be delivered to the head of the licensee not later than 15 days after the end of the inspection, who then has to sign it if he agrees to the findings and corrections in the report. If the licensee objects to sign the report a formal registered letter is sent from the inspection office. The licensee can then object to court, which makes the final decision on the outcome of what corrective actions that have to be taken.

If the inspector finds that there are violations which pose a threat to safety, that needs to be immediately corrected, the inspector can order this, but it has no legal support unless it is backed up by a formal written decision, or prescription. This prescription would be subject to the formal procedures of approval and complaint described above, which in practice means that there is no formal possibility for an inspector to enforce the request that corrective actions are immediately undertaken.

If needed, Rostekhnadzor can, in accordance with the “the Code on Administrative Violations of the Russian Federation”, in certain cases request and get a court order to suspend or prohibit any activities related to radioactive substances and radioactive waste management for up to 5 days. If a longer suspension is called for, this can be issued by the court and the duration of such suspension can last up to 90 days, after which a final court decision has to be made on the allowance of continuation of activity.

It should be noted that the court does not have to call in the responsible inspector, or any other representative from Rostekhnadzor before coming to its conclusion.

In addition to this procedure, the “Administrative regulations for the Federal Environmental, Industrial and Nuclear Supervision Service to perform its state function as to licensing of the activity in atomic energy use” (AR) sets out another procedure that can be followed. According to article 22.3.4 of the AR, if one or more violations are found, the responsible department have up to 7 days to prepare a draft decision on suspension of the licence. For this decision to enter into force it has to be signed by the deputy head of the office responsible for issuing the licence and approved and decided upon by the head of responsible department. The AR does not specify if there is a time limit on this suspension. To use this method to enforce immediate corrections, both the deputy head and the head of the office have to be present at the inspection.

There are two systems for enforcement in place which work if the licensee agrees to the corrective actions that is given by Rostekhnadzor and if there is no immediate need to enforce corrective actions. However, if an inspector finds a violation that has to be corrected immediately, this has to be performed by a suspension of the licence in accordance to the procedures given in AR, which in practice is not possible to execute on short notice.

8.2. TRANSPORT

Article 25 of Federal Law ‘On the Use of Atomic Energy’, No. 170-FZ, November 21, 1995 foresees sanctions in case of violation of safety requirements of transportation of Nuclear Material and Radioactive Sources.

According to Article 25 of Federal Law ‘On the Use of Atomic Energy’, No. 170-FZ, November 21, 1995 and Article 9.6 of the Provision on the Federal Environmental, Industrial and Nuclear Supervision Service of Russian Federation (Rostekhnadzor), approved by the Decree of the Government of Russian Federation No. 401, dated July 30, 2004. Rostekhnadzor imposes sanctions foreseen within Article 9.6 of the Code of the Russian Federation on Administrative Violations No. 195-FZ.

Only the court has the right to cancel the licence of the licensee, while Rostekhnadzor can suspend it for 5 days only.

9. REGULATIONS & GUIDES

Timely updates of regulations/guides

There are three levels of documents pertaining to regulatory requirements. The highest level relates to Federal laws, decrees of the President, and government orders. The second level pertains to regulations issued by MNRE, and the third level regards safety guides issued by the regulatory body. The issuance of regulations by MNRE was a change instituted two years ago, where previously the regulations were issued by the regulatory body.

With respect to the first level of regulatory documents, i.e., Federal laws and government orders, there is a multi-year plan to update these documents. Regarding regulations, in 2005, the regulatory body identified a limited list of regulations that needed to be updated. More recently, the regulatory body has identified additional regulations that need to be updated to reflect IAEA recommendations. With respect to safety guides, there is not a current plan for updating these documents.

While the regulatory body recognizes the importance of periodically updating its regulations and safety guides, it has not implemented a process that provides for a systematic review and update, as necessary, of these documents.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part 1 Requirement 33 states that <i>“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 technical standards and of relevant experience gained.”</i>
R23	Recommendation: MNRE and Rostekhnadzor should coordinate to provide for developing and implementing a process for the systematic and periodic review of the regulations and safety guides to update them as appropriate, based on the results of such review.

9.1. RESEARCH REACTORS

No provisions whatsoever exist in the regulations and guides pertaining to computer based system with safety relevance in nuclear research facilities. This is a consequence of the fact that the great majority of the operating nuclear research facilities have been designed and constructed before the regular application of computers in system having safety significance. In view of the fact, however, that the operational lifetime of many of such facilities shall be extended and also that there are new facilities under construction, application of computerized system with safety relevance is likely in the future.

Future use of computers in safety relevant roles is foreseen and therefore guidance or regulation on this subject may be necessary soon.

Discussion of the IRRS Review Team and Rostekhnadzor experts revealed that although operational limits and conditions are requested to be compiled by the operators of nuclear research facilities, no clear requirements on the contents of such a document have so far been set.

Requirements on the contents of the OLC ensures that operators identify the parameters and limits important for the safe operation of nuclear research facility according to the expectations of the regulatory body.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: NS-R-4 para 7.29 states that <i>“A set of OLCs important to reactor safety, including safety limits, safety system settings, limiting conditions for safe operation, requirements for inspection, periodic testing and maintenance and administrative requirements, shall be</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>established and submitted to the regulatory body for review and assessment.</i> ”
R24	Recommendation: Rostekhnadzor should specify the contents of the OLCs to be elaborated by operators of nuclear research facilities and to be submitted to Rostekhnadzor for review and assessment.

9.2. INDUSTRIAL, MEDICAL AND RESEARCH FACILITIES

Regulations and guides for the safety of radioactive sources are developed according to general procedures (Ordinance of the Government of the Russian Federation "On Approval of the Order of Development and Approval of Federal Codes and Standards in the Field of Atomic Energy Use and of List of Federal Codes and Standards in the Field of Atomic Energy Use", No. 1511 of 01.12.1997, RD-03-06-98, RD-03-06-98). In 2009 two regulations were under review. No review or development of radioactive sources safety regulations or guides is planned for 2010. According to the Rostekhnadzor declared intention to promote graded approach the plans are under preparation for the development of regulations and guides up to 2015.

It is Rostekhnadzor’s intention to use the categorization of sources (Rostekhnadzor Safety Guide RB-042-07, “Procedure for Categorizing Sealed Radionuclide Sources by Potential Hazard to Human Beings,”) as a base to ensure a more graded approach in coming reviews and development of their regulations.

For the regulation of the activities (licensing, review and inspection) with the radioactive sources Rostekhnadzor uses regulations and guides developed and approved both by MNRE/Rostekhnadzor and Ministry of Health/FMBA/Rospotrebnadzor.

Regulation development process is in place. Rostekhnadzor plans to develop and review regulations and guides for radioactive sources in accordance with a graded process.

9.3. WASTE FACILITIES

Waste acceptance criteria

There is a big amount of very low level waste which is and will be generated at different nuclear sites. For some of these sites standards have already been developed, and such good practice could be also extended to other sites. FMBA and Rospotrebnadzor are responsible for the development of norms and standards on radiation protection (e.g. NRP 99/2009 – Basic Safety Standards). The development of safety requirements for radioactive waste management in general is a responsibility of Rostekhnadzor. Up to now there are no joint activities to develop one set of regulatory documents for all types of activities and facilities by Rostekhnadzor and FMBA. It would be therefore beneficial if all mentioned authorities develop a common set of regulatory documents.

Another issue is related to waste acceptance criteria for the storage facility at SNF Lapse. After the retrieval of the spent fuel the rest of the storage tanks will be managed as a big waste package regulated by the Rostekhnadzor. The plan is to store this waste package at Saida storage facility, which is not under the regulation and supervision of Rostekhnadzor, since its activities there are regulated by Rosatom. It is also not clear if waste acceptance criteria at Saida site are known and acceptable for Rostekhnadzor. The IRRS Review Team noted that requirements for the radioactive waste packages for the rest of the Lapse have to be developed taking into account also the waste acceptance criteria at storage facilities, which are not under control of Rostekhnadzor. It should be noticed that Rostekhnadzor developed some recommendations for the elaboration of waste acceptance criteria (RB-023-02). At the same time it could be recommended to give to these recommendations the status of standard (NP).

Rostekhnadzor has developed a set of documents related to radioactive waste management. However their enforcement could be improved. There is not any special rule or guidance on developing the legal structure of these documents, i.e. on which legal level such document (standards or guidance) should be. In addition, there is not clear differentiation between the requirements for new and old facilities. The old facilities which need upgrading are not subject to the requirements from Rostekhnadzor for upgrade or improvements. The passive approach of the regulator to that issue was recognized.

IRRS Review Team understood that several of the mentioned problems will be solved by the new Law. In the mean time there are ongoing activities mentioned above that need regulatory decision to support radioactive waste management solutions. Rostekhnadzor recognizes the need to develop requirements for waste acceptance criteria for the radioactive waste management facilities and, in particular, for long term storage and disposal, after the law has been approved.

Clearance

To facilitate compliance with regulatory requirements, the regulatory body has to establish criteria for the clearance of material from regulatory control, in accordance with national policy. The authorized clearance of materials from regulatory control, after some appropriate processing and/or a sufficiently long period of storage, together with reuse and recycling of material, can be effective in reducing the amount of radioactive waste that needs further processing or storage. The operator has to ensure that these management options, if implemented, are in compliance with the conditions and criteria established in regulations or by the regulatory body.

From the answers to the self-assessment questionnaires, as well as from the interviews the IRRS Review Team clearly understood that the establishment of norms and standards for clearance criteria and requirements are under the responsibilities of FMBA. The IRRS Review Team was informed that still there is not a very clear distinction in the regulation, implementation and control of exemption and clearance.

Rostekhnadzor recognizes the wide application of the clearance concept and associated criteria in different areas of waste minimization and plans to initiate actions in coordination with other responsible organizations to apply this concept.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part5 Requirement 10 states that <i>“Processing of radioactive waste: “Radioactive material for which no further use is foreseen, and with characteristics that make it unsuitable for authorized discharge, authorized use or clearance from regulatory control, shall be processed as radioactive waste”...</i>
(2)	BASIS: WS-R-5, par 3.6 states that <i>“The responsibilities of the regulatory body include: ...— Establishing safety and environmental criteria for the decommissioning of facilities, including criteria for clearance of material during decommissioning”...</i>
R25	Recommendation: MNRE should coordinate with FMBA to develop regulations that provide for the practical application of clearance criteria and clearance levels associated with activities under Rostekhnadzor’s responsibility and control, including requirements for the release of installations and sites from regulatory control.

9.4. TRANSPORT

Article 25 of Federal Law ‘On the Use of Atomic Energy’, No. 170-FZ, November 21, 1995 foresees development, approval and implementation of norms and regulations in the field of use of atomic energy, including transport of Nuclear Material and Radioactive Sources. The Ministry of Natural Resources and Environment of the Russian Federation (MNRE) is the federal executive body exercising functions on normative and legal regulation in the field of safety in the field of use of atomic energy.

In accordance with Article 25 of Federal Law ‘On the Use of Atomic Energy’, No. 170-FZ, November 21, 1995 the MNRE puts in force federal norms and regulations. The federal norms and regulations ‘The Safety Regulations for Transport of Radioactive Material’ NP-053-04 are used in the field of transportation of Nuclear Material and Radioactive Sources. This document is the implementation of the IAEA TS-R-1 ‘Regulations for the Safe Transport of Radioactive Material’, edition 2000 and contains only technical requirements without any authorization (licensing) activities.

The necessity for competent authority approvals of packages, shipments, special form material, special arrangement etc, according to para 802 of TS-R-1 is written in Federal Law No. 317-FZ “On State Corporation on Atomic Energy ‘Rosatom”, December 1, 2007 and the provision of the State Competent Authority on nuclear and radiation safety during transportation of Nuclear Material and Radioactive substances and their products approved by the Decree of the Government of Russian Federation No. 204, March, 19 2001 for which Rosatom is responsible for.

In addition there are also other provisions for the transport of Nuclear Material and Radioactive Sources in the Provision on the Federal Medical and Biological Agency, approved by the Decree of the Government of Russian Federation No. 206, dated April 11, 2005 and in the Provision on the Ministry of Transport of the Russian Federation, approved by the Decree of the Government of Russian Federation No. 395, dated July 30, 2004.

Because the Russian Federation is a member of:

- ADR (for the road transport)
- ICAO International Civil Aviation Organization (for the air transport)
- IMO International Maritime Organization (for the sea transport)

which are the international agreements for the transport of dangerous goods (inclusive class 7 – radioactive material) and these are binding documents for the international transport of radioactive material and bearing in mind, that these agreements had implemented the requirement of TS-R-1 of IAEA in their regulations it has to be discussed between all stakeholders, which laws, ordinances and technical regulations have to be established or can be eliminated.

It was discussed with the counterparts the current international efforts of harmonization and the possibility to simplify national regulations by simply making international agreements applicable for national transports through a national law. The counterparts informed the IRRS Review Team, that in the Russian Federation a law for the transport of dangerous goods doesn’t exist.

There were discussions on the need for update the state variation, which formally is the responsibility of the ministry of transport. If cooperation among regulatory bodies would have been more effective, this would be straight forward.

There is a lack of an integrated regulation for the transport of all dangerous goods, including radioactive material in the Russian Federation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: TS-R-1 para 106 and “International Agreements on the transport of Dangerous Goods states that <i>“These regulations apply to the transport of radioactive material by all modes on land, water or in the air.”</i>
S33	Suggestion: MNRE should take initiative to establish a law for the transport of all dangerous goods (including radioactive material) with the responsibilities of all parties involved and the process of issuing certificates for packages, shipment, etc .in accordance with para 802 of the IAEA Regulations for the Safe Transport of Radioactive Material, TS-R-1.
S34	Suggestion: Rostekhnadzor should coordinate with the relevant authorities to update the “State variations” for the Russian Federation in the ICAO – Technical Instruction (international regulations for the transport of dangerous goods by air).

IRRS

Integrated Regulatory
Review Service



IAEA

International Atomic Energy Agency

Moscow
14-28 November 2009

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
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12. Heikki REPONEN	Radiation and Nuclear Safety Authority (STUK)	Heikki.Reponen@stuk.fi
13. Greg RZENTKOWSKI	Canadian Nuclear Safety Commission (CNSC)	Greg.Rzentkowski@cnsccsn.gc.ca
14. Gerhard SCHOEN	Swiss Federal Nuclear Safety Inspectorate (ENSI)	Gerhard.Schoen@ensi.ch
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16. Zhongtang WANG	National Nuclear Safety Administration (NNSA)	Wang_zhong_tang@yahoo.com.cn
17. Erik WELLEMAN	Swedish Radiation Protection Authority (SSI)	erik.welleman@ssm.se
18. Juergen WOLF	Bundesministerium fuer Umwelt, Naturschutz und Reaktorsicherheit (BMU)	Juergen.Wolf@bmu.bund.de
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OFFICIAL ASN LIAISON OFFICER:		
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2. Andrej PESHKOV	Ministry of Natural Resources and Environment of the Russian Federation (MNRE)	aspeshkov@mnr.gov.ru

APPENDIX II – MISSION PROGRAMME

MISSION PROGRAMME		
Sunday, 15 November, 2009		
IRRS Opening IRRS Review Team Meeting		
14:00 - 18:00	<p><i>Opening Remarks by the IRRS Team Leader (Mr. Laaksonen)</i> <i>Introduction by Jukka Laaksonen, and Ramzi Jammal</i> <i>Self introduction of all Attendees</i> <i>Introductory words by Mr. Peshkov.</i> <i>Presentation on the IRRS Methodology (Mr. Caruso)</i> <i>Presentation on Reporting (Mr. Mansoux)</i> <i>Presentation Mission conduct/review (Mr. Laaksonen)</i> <i>First Impression from experts arising from the Advanced Reference Material (ARMS)</i></p>	<i>IRRS Review Team Liaison Officers</i>
Monday, 16 November, 2009		
IRRS Entrance Meeting		
09:30 - 17:00	<p><i>Opening Remarks by Deputy Minister Mr. Lev</i> <i>Opening Remarks by Chairman of Rostechnadzor Mr. Kutin</i> <i>Opening Remarks by the IRRS Team Leader Mr. Laaksonen</i> <i>Self-Introductory of the IRRS Team</i> <i>IRRS Team Leader presentation on the Russian IRRS Process and Objective</i> Counterpart Presentations: Overview of the Russian regulatory approach <ul style="list-style-type: none"> - <i>Module I, Summary of Conclusions raised from the Self-Assessment</i> - <i>Module II, Summary of Conclusions raised from the Self-Assessment</i> - <i>Module III, Summary of Conclusions raised from the Self-Assessment</i> - <i>Module IV, Summary of Conclusions raised from the Self-Assessment</i> - <i>Module V, Summary of Conclusions raised from the Self-Assessment</i> - <i>Module VI, Summary of Conclusions raised from the Self-Assessment</i> - <i>Module VII, Summary of Conclusions raised from the Self-Assessment</i> - <i>Module VIII, Summary of Conclusions raised from the Self-Assessment</i> </p>	<i>IRRS Team MNRE Rostechnadzor</i>
17:00 - 18:45	Daily IRRS Team Meeting	<i>IRRS Team Liaison Officers</i>
Tuesday, 17 November, 2009		
Daily Discussions / Interviews		
09:00 – 17:00	<p><i>Review Area 1 – Responsibilities and functions of the government</i> Policy Discussion on: <ul style="list-style-type: none"> - <i>State policy in the field of safety assurance of the use of nuclear energy</i> - <i>Resources and financing of regulatory body</i> - <i>Independence of regulatory decision making on safety issues</i> </p>	<i>IRRS (GEN) MNRE Rostechnadzor</i>
09:00 – 17:00	<i>Review Area 5 – Authorization of facilities and activities by the regulatory body, Nuclear Power Plants</i>	<i>IRRS (NPP1) & (NPP2)</i>

MISSION PROGRAMME		
		MNRE Rostechnadzor
09:00 – 17:00	<i>Review Area 5 – Authorization of facilities and activities by the regulatory body, Research Reactors</i>	IRRS (RR) MNRE Rostechnadzor
09:00 – 17:00	<i>Review Area 5 – Authorization of facilities and activities by the regulatory body, Fuel Cycle Facilities.</i>	IRRS (FCF) MNRE Rostechnadzor
09:00 – 17:00	<i>Review Area 5 – Authorization of facilities and activities by the regulatory body, Waste</i>	IRRS (W) MNRE Rostechnadzor
09:00 – 17:00	<i>Review Area 5 – Authorization of facilities and activities by the regulatory body, Sources and Transport</i>	IRRS (S&T) MNRE
	<i>Review Area 6 – Review and assessment, Sources and Transport</i>	Rostechnadzor
	<i>Review Area 9 – Regulations and guides, Sources and Transport</i>	
17:00 -	Daily IRRS Team Meeting	IRRS Team Liaison Officers
Wednesday, 18 November 2009		
Daily Discussions / Interviews		
09:00 – 17:00	<i>Review Area 1 – Responsibilities and functions of the government,</i>	IRRS (GEN)
	<i>Review Area 2 – Global Safety Regime</i>	MNRE
	<i>Review Area 3 – Responsibilities and functions of the regulatory body</i>	Rostechnadzor
09:00 – 17:00	<i>Review Area 7 – Inspection, Nuclear Power Plants</i>	IRRS (NPP1) MNRE Rostechnadzor
09:00 – 17:00	<i>Review Area 6 – Review and assessment, Nuclear Power Plants</i>	IRRS (NNP2) MNRE Rostechnadzor
09:00 – 17:00	<i>Review Area 7 – Inspection, Research Reactors</i>	IRRS (RR) MNRE Rostechnadzor
09:00 – 17:00	<i>Review Area 7 – Inspection, Fuel Cycle Facilities</i>	IRRS (FCF) MNRE Rostechnadzor
09:00 – 17:00	<i>Review Area 7 – Inspection, Waste</i>	IRRS (W) MNRE Rostechnadzor
09:00 – 17:00	<i>Review Area 5 – Authorization of facilities and activities by the regulatory body, Sources in Medical Facilities</i>	IRRS (S&T) MNRE
	<i>Review Area 6 – Review and Assessment, Sources in Medical Facilities</i>	Rostechnadzor
	<i>Review Area 7 – Inspection, Sources in Medical Facilities</i>	
	<i>Review Area 8 – Enforcement, Sources in Medical Facilities</i>	
	<i>Review Area 9 – Regulations and Guides, Sources in Medical Facilities</i>	
17:00 -	Daily IRRS Team Meeting	IRRS Team

MISSION PROGRAMME

Liaison Officers

Thursday, 19 November 2009

Daily Discussions / Interviews

	<i>Review Area 4 – Management system of the Regulatory Body</i>	<i>IRRS (GEN) MNRE Rostechnadzor</i>
	Review Area 1 – Responsibilities and functions of the government (req 10) and policy discussion on this <ul style="list-style-type: none"> National strategy and programme for nuclear waste management 	
	<i>Review Area 8 – Enforcement and Review Area 9 – Regulations and Guides</i>	<i>IRRS (NPP1) MNRE Rostechnadzor</i>
	<i>Review Area 8 – Enforcement and Review Area 9 – Regulations and Guides</i>	<i>IRRS (FCF) MNRE Rostechnadzor</i>
	<i>Review Area 8 – Enforcement</i> <i>Review Area 9 – Regulations and Guides</i>	<i>IRRS (RR) MNRE Rostechnadzor</i>
	<i>Review Area 8 – Enforcement and Review Area 9 – Regulations and Guides</i>	<i>IRRS (W) MNRE Rostechnadzor</i>
	<i>Review Area 6 – Review and assessment</i>	<i>IRRS (NNP2) MNRE Rostechnadzor</i>
	<i>Review Area 5 – Authorization of facilities and activities by the regulatory body, Transport of Radioactive Material</i>	<i>IRRS (S&T) MNRE</i>
	<i>Review Area 6 – Review and assessment, Transport of Radioactive Material</i>	<i>Rostechnadzor</i>
	<i>Review Area 7 – Inspection, Transport of Radioactive Material</i>	
	<i>Review Area 8 – Enforcement, Transport of Radioactive Material</i>	
	<i>Review Area 9 – Regulations and Guides, Transport of Radioactive Material</i>	
17:00 -	Daily IRRS Team Meeting	<i>IRRS Team Liaison Officers</i>

Friday, 20 November, 2009

Daily Discussions / Interviews and Site Visits

09:00 – 12:30	<i>Continuation of Discussions</i>	<i>IRRS Team MNRE Rostechnadzor</i>
12:30 – 16:00	<i>Site Visit to SEC NRS</i>	<i>IRRS (GEN), (NPP2), (FCF) MNRE Rostechnadzor</i>
	<i>Site Visit to Kalinin NPP</i>	<i>IRRS (NPP1)</i>

MISSION PROGRAMME		
		<i>MNRE Rostekhnadzor</i>
	<i>Site Visit to MEPHI</i>	<i>IRRS (RR) MNRE Rostekhnadzor</i>
	<i>Site Visit to Radon</i>	<i>IRRS (W) MNRE Rostekhnadzor</i>
	<i>Site Visit to Hospital no. 85</i>	<i>IRRS (S&T) MNRE Rostekhnadzor</i>
17:00 -	Daily IRRS Team Meeting	<i>IRRS Team Liaison Officers</i>
Saturday, 21 November, 2009		
Daily Discussions		
	Report writing	<i>IRRS Team</i>
	Daily IRRS Team Meeting	
Sunday, 22 November, 2009		
Daily Discussions		
	Report writing	<i>IRRS Team</i>
Monday, 23 November, 2009		
Daily Discussions		
09:30-12:30	Policy discussion on Regulations and Guides	<i>IRRS Team MNRE Rostekhnadzor</i>
14:00 -	Daily IRRS Team Meeting – Review of the Mission report	<i>IRRS Team</i>
Tuesday, 24 November, 2009		
Daily Discussions		
09:00-12:30	Review of Findings with the Russian Counterparts, in respective groups	<i>IRRS Team MNRE Rostekhnadzor</i>
14:00-17:00	Revision of Mission Report after comments have been received	<i>IRRS Team</i>
17:00 -	Daily IRRS Team Meeting – Discussion on draft Mission Report	<i>IRRS Team Liaison Officers</i>
Wednesday, 25 November, 2009		
Review of Mission report and, mission report handover		
09:00-15:00	Daily IRRS Team Meeting – Preparation of Executive Summary	<i>IRRS Team</i>
15:00	Draft Mission Report handed to Russian Counterpart	
Thursday, 26 November, 2009		
Plenary Session and Preparation for the exit meeting		
09:30-12:30	Plenary Meeting on IRRS Mission Report to the Russian Federation	<i>IRRS Team MNRE Rostekhnadzor</i>

MISSION PROGRAMME

14:00 – 17:00	Discussion on final conclusions to be presented	<i>IRRS Team</i>
	Preparation for Exit Meeting	<i>Liaison Officers</i>
Friday, 27 November, 2009		
EXIT MEETING and PRESS CONFERENCE		
11:00 – 12:00	Exit Team Meeting	<i>IRRS Team MNRE Rostechnadzor Rosatom</i>
12:00 – 12:30	Press-conference of the management of MNRE, Rostechnadzor, Rosatom, IAEA	<i>IRRS TL. & IAEA MNRE Rostechnadzor Rosatom</i>
12:30 -	Lunch hosted on behalf of the Minister of Natural Resources and Environment of the Russian Federation Yu.P.Trutnev	<i>All Participants</i>

APPENDIX III – SITE VISITS

SITES VISITED
1. Kalinin NPP.
2. Mayak plant
3. MEPHI research reactor
4. Moscow Radon waste management facility
5. Nuklon facility

APPENDIX IV – LIST OF COUNTERPARTS

	AREAS	IRRS EXPERTS	MNRE Counterpart	Rostechnadzor Counterpart
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	J. Laaksonen R. Jammal M. Asty J.C. Lentijo J. Wolf	D.A. Brunin K.S. Kornienko I. Shumakov	V.S. Bezzubtsev V.B.Kuzmichev
2.	GLOBAL NUCLEAR SAFETY RÉGIME	J. Laaksonen R. Jammal M. Asty J.C. Lentijo J. Wolf	D.A. Brunin K.S. Kornienko	V.S. Bezzubtsev V.B.Kuzmichev
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	J. Laaksonen R. Jammal M. Asty J.C. Lentijo J. Wolf	D.A. Brunin K.S. Kornienko	V.S. Bezzubtsev V.B.Kuzmichev
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY	J. Laaksonen R. Jammal M. Asty J.C. Lentijo J. Wolf	D.A. Brunin K.S. Kornienko	V.S. Bezzubtsev V.B.Kuzmichev
5.	AUTHORIZATION			
	Nuclear Power Plants	M. Dapas P. Krs H. Reponen	V.P. Snegeriv A.V. Prikhodko	M.I. Miroshnichenko V.A. manakov A.N. Ryazanov

	AREAS	IRRS EXPERTS	MNRE Counterpart	Rostechnadzor Counterpart
		G. Rzentkowski G. Schoen A. Nacic		
	Research Reactors	I. Lux Z. Wang	V.P. Snegirev	A.I.Sapozhnikov S.I.Morozov
	Fuel Cycle Facilities	M. Bassett	A.V.Prikhodko	A.A.Lavrinovich S.N.Udodov
	Industrial, Medical and Research Facilities	E. Welleman O. Makarovska H. Mansoux	S.A.Sitnikov	V.Ya.Reka A.D.Golubev
	Waste Facilities	L. Jova Sed M. Sneve J. Raicevic	S.A.Sitnikov	V.A.Neretin V.I.Skugarov
	Transport	C. Fasten H. Mansoux	S.A.Sitnikov	V.Ya.Reka A.D.Golubev S.A.Ulanov V.I.Skugarov
6.	REVIEW AND ASSESSMENT			
	Nuclear Power Plants	M. Dapas P. Krs H. Reponen G. Rzentkowski G. Schoen A. Nacic	V.P.Snegirev A.V.Prikhodko	M.I.Miroshnichenko V.A.Manakov V.A.Grivizirsky S.N.Bogdan
	Research Reactors	I. Lux Z. Wang	V.P.Snegirev	A.I.Sapozhnikov S.I.Morozov

	AREAS	IRRS EXPERTS	MNRE Counterpart	Rostechnadzor Counterpart
	Fuel Cycle Facilities	M. Basset A. Nacic	A.V.Prikhodko	A.I.Kislov A.A.Lavrinovich
	Industrial, Medical and Research Facilities	E. Welleman O. Makarovska H. Mansoux	S.A.Sitnikov	V.Ya.Reka A.D.Golubev
	Waste Facilities	L. Jova Sed M. Sneve J. Raicevic	S.A.Sitnikov	V.A.Neretin V.I.Skugarov
	Transport	C. Fasten H. Mansoux	S.A.Sitnikov	V.Ya.Reka A.D.Golubev S.A.Ulanov V.I.Skugarov
7.	INSPECTION			
	Nuclear Power Plants	M. Dapas P. Krs H. Reponen G. Rzentkowski G. Schoen A. Nacic	A.V.Prikhodko	V.A.Grivizirsky
	Research Reactors	I. Lux Z. Wang	V.P.Snegirev	A.I.Sapozhnikov S.I.Morozov
	Fuel Cycle Facilities	M. Basset A. Nacic	A.V.Prikhodko	A.A.Lavrinovich
	Industrial, Medical and Research Facilities	E. Welleman O. Makarovska H. Mansoux	S.A.Sitnikov	V.Ya.Reka A.D.Golubev S.A.Ulanov

	AREAS	IRRS EXPERTS	MNRE Counterpart	Rostechnadzor Counterpart
				V.I.Skugarov A.I.Kislov
	Waste Facilities	L. Jova Sed M. Sneve J. Raicevic	S.A.Sitnikov	V.A.Neretin A.I.Kislov
	Transport	C. Fasten H. Mansoux		V.Ya.Reka A.D.Golubev
8.	ENFORCEMENT			
	Nuclear Power Plants	M. Dapas P. Krs H. Reponen G. Rzentkowski G. Schoen A. Nacic	A.V.Prikhodko	V.A.Grivizirsky
	Research Reactors	I. Lux Z. Wang	V.P.Snegirev	A.I.Sapozhnikov S.I.Morozov
	Fuel Cycle Facilities	M. Basset A. Nacic	A.V.Prikhodko	A.A.Lavrinovich S.N.Udodov
	Industrial, Medical and Research Facilities	E. Welleman O. Makarovska H. Mansoux	S.A.Sitnikov	S.A.Ulanov V.I.Skugarov A.I.Kislov
	Waste Facilities	L. Jova Sed M. Sneve J. Raicevic	S.A.Sitnikov	V.A.Neretin A.I.Kislov S.N.Udodov
	Transport	C. Fasten		

	AREAS	IRRS EXPERTS	MNRE Counterpart	Rostechnadzor Counterpart
		H. Mansoux		
9.	REGULATIONS AND GUIDES			
	Nuclear Power Plants	M. Dapas P. Krs H. Reponen G. Rzentkowski G. Schoen A. Nacic	A.V.Prikhodko	V.A.Grivizirsky
	Research Reactors	I. Lux Z. Wang	V.P.Snegirev	A.I.Sapozhnikov S.I.Morozov
	Fuel Cycle Facilities	M. Basset A. Nacic	A.V.Prikhodko	A.A.Lavrinovich S.N.Udodov
	Industrial, Medical and Research Facilities	E. Welleman O. Makarovska H. Mansoux		
	Waste Facilities	L. Jova Sed M. Sneve J. Raicevic	S.A.Sitnikov	V.A.Neretin A.I.Kislov S.N.Udodov
	Transport	C. Fasten H. Mansoux	S.A.Sitnikov	V.Ya.Reka A.D.Golubev S.A.Ulanov V.I.Skugarov

APPENDIX V – RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	R1	<u>Recommendation:</u> The government of the Russian Federation should continue the work on the enhancement of its legislation in accordance with IAEA Safety Standards to provide clear and sustainable nuclear and radiation safety regulations for all nuclear activities, including radioactive waste management, as well as to remove the restrictions on frequency and duration of the inspections of the regulating authorities.
		R2	<u>Recommendation:</u> The government of the Russian Federation should develop and implement a financing mechanism which ensures adequate resources for nuclear and radiation safety regulation including competent staff and the necessary financing for independent safety reviews that are a prerequisite for licensing decisions, taking into account the increasing amount of nuclear energy utilization in the Russian Federation.
		S1	<u>Suggestion:</u> A more clear structure and integration of the legal framework should be considered for better effectiveness of the nuclear regulations, considering the different roles and responsibilities of all involved parties for safety, and more attention should be given to a graded approach to safety considering the wide range of facilities and activities included.
		R3	<u>Recommendation:</u> Regarding the special need for the coordination of radiation protection issues, including those related to the practical application of the radiation protection optimization principle, the bilateral agreements between Rostekhnadzor on one side, and FMBA and Rospotrebnadzor on the other side, should be encouraged and given a high priority.
		S2	<u>Suggestion:</u> The coordination between the different regulatory authorities should go further than developing bilateral

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			agreements. In particular, common actions, such as inspections, could help avoiding conflicting requirements being placed on the authorised parties.
		S3	Suggestion: As part of continuous improvement, Rostekhnadzor, FMBA and Rospotekhnadzor should analyze the experience gained in the practical application of their agreements and, if appropriate, use this experience for the development of a joint proposal to adapt the necessary provisions of the State to better consolidate the coordination approach.
		S4	Suggestion: Rostekhnadzor is encouraged to extend its cooperation agreement with EMERCOM beyond NPPs to other facilities.
		R4	Recommendation: MNRE should take into account that, for improvement and development of the federal legislation and optimization of the structure of the State authorities, it is necessary to consider the issue of effective distribution of all regulatory functions (competent authority approvals) addressed in the IAEA Regulations for the Safe Transport of Radioactive Material, TS-R-1, para 802, namely approval for packages, shipments, special form material, special arrangements etc. between independent federal executive authorities.
		S5	Suggestion: MNRE and Rostekhnadzor should take initiative to enhance their cooperation with the Ministry of Transport, EMERCOM and FMBA to avoid the duplication of the functions of competent authorities, e.g. by establishing of a Memorandum of Understanding.
		S6	Suggestion: The government of the Russian Federation should develop and implement the necessary legal and regulatory framework for the control and supervision of the remediation to be undertaken for the identified past practices and installations that need remedial actions. This should include the necessary

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			steps to identify all entities responsible for decontamination. The government should set financial requirements and mechanisms for the remediation activities, for clearance from the regulatory control and for the establishment of the institutional control where needed.
		S7	Suggestion: MNRE and Rostechнадзор are encouraged to establish formal cooperation and exchange of information with EMERCOM and other responsible authorities to provide an effective State system for gaining control over orphan radioactive sources. This should be done through clear allocation of responsibilities and definition of mechanisms of coordination and interaction of national competent authorities.
		S8	Suggestion: MNRE should specify the tasks assigned to Rosatom in order to implement the law on radioactive waste management. MNRE should also promote identification of the regulatory responsibilities in all areas included in the law on radioactive waste management.
		R5	Recommendation: The Ministry of Natural Resources and Environment should promote the elaboration and approval of an overall legal and regulatory framework for decommissioning in accordance with the IAEA Safety Standards.
2.	GLOBAL NUCLEAR SAFETY RÉGIME	G1	Good Practice: The Russian Federation is making an extensive use of the IAEA Safety Standards in developing its regulations and guides.
		S9	Suggestion: Rostechнадзор should evaluate whether its practice in feedback of operating experience is in line with international recommendations and could consider requiring the systematic collection, analysis and dissemination of operating experience of all nuclear facilities, especially for the research reactors.
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY	R6	Recommendation: MNRE and Rostechнадзор should develop and submit to the Government of Russia the Russian Federation

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	BODY		a proposal on the human resources required to cope with the nuclear regulatory duties foreseen in relation with construction of the new reactors also in view of the requirement of not jeopardizing the supervision of the safety of existing nuclear facilities.
		S10	<u>Suggestion:</u> MNRE and Rostechнадзор are should develop and implement a systematic approach to training, following the IAEA guidance in this field.
		G2	<u>Good Practice:</u> The internal certification council activity is considered as a good practice.
		R7	<u>Recommendation:</u> Rostechнадзор should ensure that it has sufficient staff capable of guiding and evaluating independent regulatory reviews and assessments performed by technical support organizations.
		S11	<u>Suggestion:</u> MNRE and Rostechнадзор should consider the establishment of an independent advisory body to support regulatory decision making for substantiation of decisions, transparency and independence.
		S12	<u>Suggestion:</u> MNRE and Rostechнадзор should conduct a communication efficiency analysis and prepare and implement communications strategy. This should include improvement of the websites by introducing separate and easily found sections for nuclear and radiation safety topics.
		S13	<u>Suggestion:</u> MNRE together with Rostechнадзор should consider the reasonability and possibility of the use of the information from the register of the state system of accounting and control in the Rostechнадзор management system RAIS (Regulatory Authority Information System).
		G3	<u>Good Practice:</u> Format of the records of the radioactive sources inside RAIS (Regulatory Authority Information System) is the

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			same as in the IAEA RAIS and thus provides possibility of exchange of radioactive source information between the Russian Federation and the IAEA.
		G4	Good Practice: The IRRS Review Team recognized as a good practice the existence of such comprehensive and detailed records describing the situation at the facilities.
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY	R8	Recommendation: MNRE and Rostechнадзор should establish their respective comprehensive management systems in accordance with IAEA GS-R-3 and amend RD-03-29-2008 in order to reflect current organizational structure. The management system of regulatory body should provide a clear description of the regulatory review and inspection processes, as well as for the analysis of reportable events.
		S14	Suggestion: Rostechнадзор should consider developing and implementing a system capable of tracking the completion status of regulatory actions in order to provide a corresponding regulatory overview.
		S15	Suggestion: Rostechнадзор should develop a quality declaration that reflects the current activities.
5.	AUTHORIZATION	R9	Recommendation: MNRE and Rostechнадзор should evaluate its practice of licensing third party/external organizations that provide services and products to licensees to ensure that this approach is not contrary to the principle that the licensee's primary responsibility to ensure safety lies with the licensee .
		R10	Recommendation: The government of the Russian Federation should identify the legal procedure for removing restrictions on time limit prescribed for completion of a safety review prior to the granting of an authorization for a nuclear facility or activity. The safety review should be commensurate with the stage in the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity, in

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			accordance with common practice in other IAEA Member States.
		G5	Good Practice: Rostechnadzor's approach to assessing the competence of senior technical and plant managers is a good practice.
		R11	Recommendation: MNRE should take the necessary measures to establish the qualification requirements for personnel holding key positions in the safe operation of nuclear research facilities. Rostechnadzor should assess the training and retraining of persons holding key positions in the safe operation of nuclear research facilities and should include the necessary training in the operating licence of the facilities.
		S16	Suggestion: Rostechnadzor should consider the possibility of establishing a procedure to determine the period of licence renewal for fuel cycle facilities.
		R12	Recommendation: For activities with radioactive sources, MNRE and Rostechnadzor should prepare a proposal to change the licensing requirements so that a graded approach is applied systematically, thus avoiding unnecessary administrative burdens.
		S17	Suggestion: Rostechnadzor should establish and implement criteria, internal procedures and guidance on the types, number and validity of licences that are needed by applicants, and in particular should consider if licensing is needed for all or only some of the stages in the life-time of a facility where radioactive sources are handled, i.e. siting, construction, operation and decommissioning.
		S18	Suggestion: MNRE and Rostechnadzor should establish formal cooperation and exchange of information with the Federal Service for Export and Technological Control to provide for full and effective implementation of the export and import provisions of the Code of Conduct on the Safety and Security of

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			Radioactive Sources.
		S19	Suggestion: Rostekhnadzor should include in all licences for operation of radioactive waste management facilities the waste activity and volume limits for the facility and other limits, conditions and controls needed for the safe operation of the facility.
		R13	Recommendation: MNRE should clarify the body that will regulate and control discharges and releases and should establish limits for the discharges and releases of radioactive substances from each nuclear or radiation facility and activity.
6.	REVIEW AND ASSESSMENT	R14	Recommendation: The Government of the Russian Federation should establish legal provisions to require the conduct by the operating organization of periodic safety reviews throughout the operational lifetime of major nuclear facilities, including nuclear power plants, research reactors and fuel cycle facilities, in accordance with the IAEA Safety Standards. The systematic safety re-assessment should be performed with a sufficient periodicity to demonstrate an adequate level of safety at the facility, using a graded approach with account taken of the potential magnitude and nature of the hazard associated with the particular facility. The resulting safety improvements should be legally enforceable.
		S20	Suggestion: Rostekhnadzor should ensure effective oversight of licensee safety culture, including the development and implementation of a method to systematically assess indicators addressing safety culture.
		R15	Recommendation: Rostekhnadzor should formalize its process via procedure for conducting a periodic integrated assessment of licensee safety performance, including definition of the scope, specification of how the assessment should be conducted, the manner of communicating the assessment results, and the use of

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			the assessment results in formulating appropriate strategies for future regulatory oversight of the licensee.
		R16	<u>Recommendation:</u> Rostechnadzor should develop a safety classification system for plant modifications, including those that do not require changes to licence conditions, in order to assist in determining the degree of regulatory assessment required before approving the modification.
		S21	<u>Suggestion:</u> Rostechnadzor should update policy statement in order to: <ul style="list-style-type: none"> - define the role of the PSA in integrated decision making, - ensure that the PSA is consistently used for the assessment of events and plant modifications, and - consider potential future PSA applications in accordance with NS-R-1, paras 5.2, 5.73.
		S22	<u>Suggestion:</u> Rostechnadzor should consider supporting the implementation of the updated policy statement on the use of PSA by a pilot study for a nuclear power plant, focusing on the evaluation of events (for a specific time interval), operational limits and conditions, and the importance of correct safety classification of components
		R17	<u>Recommendation:</u> MNRE should establish explicit requirements to ensure that the results and analysis of all stages of the commissioning programme are submitted for review and assessment to Rostechnadzor.
		S23	<u>Suggestion:</u> Rostechnadzor should, as part of the licence condition, request the operators of nuclear research facilities to submit the safety analysis report for review after its <u>periodic</u> revision.
		R18	<u>Recommendation:</u> In the licence review of each research reactor, Rostechnadzor should consider the need to establish an independent safety committee supporting the reactor manager,

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			and if appropriate, include the requirement of such a safety committee in the licence OLC.
		S24	Suggestion: Rostechнадзор should continue to explore how probabilistic assessment techniques can be developed and used to assess the safety of category 1 fuel cycle facilities.
		R19	Recommendation: MNRE and Rostechнадзор should develop requirements for the safety assessment and safety case for different types of radioactive waste management facility that do not yet have proper requirements. These requirements to be developed should address separately the facilities that already exist and those that will be built in the future. In implementing this recommendation, Rostechнадзор should consider the current actual status of existing radioactive waste storage facilities intended either for interim use only, or for final disposal.
7.	INSPECTION	R20	Recommendation: The government of the Russian Federation should pursue all means to make changes in Federal law No. 294 that would establish the necessary conditions for supervision of nuclear and radiation safety in accordance with the IAEA safety standards. In the same connection other currently existing limitations on independent inspection activities should also be eliminated.
		S25	Suggestion: Rostechнадзор should consider developing a programme or process to ensure resident inspector objectivity for continuing unbiased and fully independent assessment of the licensee's safety performance.
		R21	Recommendation: Rostechнадзор should thoroughly evaluate its approach to the inspection function to determine if the current approach is creating a situation where Rostechнадзор inspections are providing a substitute for quality control measures, which are the primary responsibility of the operating organization. The Rostechнадзор should initiate changes to its inspection

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			programme procedures as appropriate.
		R22	<u>Recommendation:</u> Rostechnadzor should evaluate its approach to the inspection function and determine if it should include more observation and assessment of practical activities conducted by the licensee instead of mostly focusing on document/procedure compliance, This would increase the efficiency and effectiveness of the inspection programme.
		S26	<u>Suggestion:</u> Rostechnadzor should also consider planning for inspections a period longer than one year to provide a comprehensive view over all the issues to be reviewed and progress made by the inspected facilities in the medium and long term.
		S27	<u>Suggestion:</u> Rostechnadzor should consider documenting its new practice with respect to comprehensive inspections, so that inspection of licensees or operating organizations are separate from, and independent of, any internal audit of regional offices.
		S28	<u>Suggestion:</u> Rostechnadzor should consider whether there is benefit in including in its comprehensive inspection teams some inspectors with detailed regulatory experience of other types of nuclear facilities to provide fresh insights and transfer good practice.
		S29	<u>Suggestion:</u> Rostechnadzor headquarters should complement and broaden its instructions on inspections to support full compliance assurance by a graded approach throughout the regions.
8.	ENFORCEMENT	S30	<u>Suggestion:</u> MNRE should initiate changes to the respective legislation in order to ensure that Rostechnadzor has the ability to issue to major operating organizations appropriate enforcement actions that are commensurate with the seriousness of the non-compliances.

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S31	Suggestion: Rostekhnadzor should clarify the actual legal background of enforcement, and should make it clear to every member of the regulatory body having any role in enforcement activities.
		S32	Suggestion: Rostekhnadzor management should emphasize the use of sanctions on the licensee rather than on individuals as a means of holding the licensee accountable for preventing recurrence of non-compliances. This management policy should be clearly communicated to Rostekhnadzor inspection staff.
9.	REGULATIONS AND GUIDES	R23	Recommendation: MNRE and Rostekhnadzor should coordinate to provide for developing and implementing a process for the systematic and periodic review of the regulations and safety guides to update them as appropriate, based on the results of such review.
		R24	Recommendation: Rostekhnadzor should specify the contents of the OLCs to be elaborated by operators of nuclear research facilities and to be submitted to Rostekhnadzor for review and assessment.
		R25	Recommendation: MNRE should coordinate with FMBA to develop regulations that provide for the practical application of clearance criteria and clearance levels associated with activities under Rostekhnadzor's responsibility and control, including requirements for the release of installations and sites from regulatory control.
		S33	Suggestion: MNRE should take initiative to establish a law for the transport of all dangerous goods (including radioactive material) with the responsibilities of all parties involved and the process of issuing certificates for packages, shipment, etc .in accordance with para 802 of the IAEA Regulations for the Safe Transport of Radioactive Material, TS-R-1.
		S34	Suggestion: Rostekhnadzor should coordinate with the relevant

	AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			authorities to update the “State variations” for the Russian Federation in the ICAO – Technical Instruction (international regulations for the transport of dangerous goods by air).

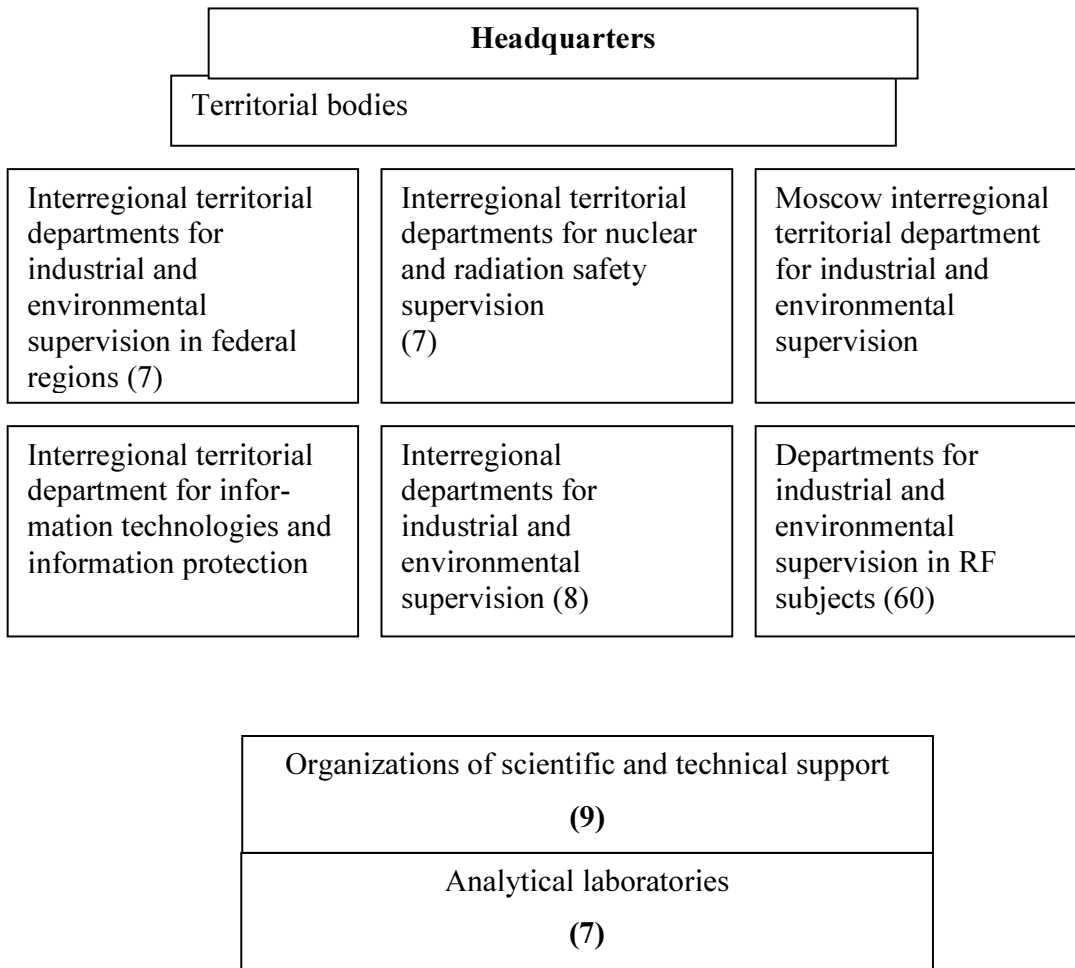
APPENDIX VI – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

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

**APPENDIX VII – MNRE AND ROSTECHNADZOR REFERENCE MATERIAL USED FOR
THE REVIEW**

- [1] IRRS Self-Assessment Report
- [2] Module I - Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety and Management System for the Regulatory Body
- [3] Module II - Responsibilities and Functions of the Regulatory Body
- [4] Module III - Organization of the Regulatory Body
- [5] Module IV - Activities of the Regulatory Body – Authorization by the Regulatory Body
- [6] Module V - Activities of the Regulatory Body – Review and Assessment
- [7] Module VI - Activities of the Regulatory Body – Inspection and Enforcement
- [8] Module VII - Activities of the Regulatory Body – Development of Regulations and Guides
- [9] Module VIII - Management System for the Regulatory Body
- [10] Legislative and Regulatory References of Self-Assessment
- [11] Replies to Safety Requirements Questionnaire DS316 “Safety of Fuel Cycle Facilities”
- [12] Questionnaire on Transportation (TS-R-1)
- [13] Code of Conduct (Radioactive sources)
- [14] Questions of NS-R-1
- [15] NS-R-2 Operation
- [16] NS-R-4 Research Reactors
- [17] Public Exposure and Waste management

APPENDIX VIII – ORGANIZATIONAL CHART ROSTECHNADZOR



APPENDIX IX – ORGANIZATIONAL CHART MNRE



**Ministry of Natural Resources and Environment
of the Russian Federation**

Structure of supervision for nuclear and radiation safety

