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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION

TO THE

CZECH REPUBLIC

Prague, Czech Republic

16 to 23 May 2017

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY







INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP REPORT TO THE CZECH REPUBLIC

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Mission date: 16 to 23 May 2017

Regulatory body: SÚJB - State Office for Nuclear Safety

Location: Senovážné náměstí 9, 110 00 Prague 1, Czech Republic

Regulated facilities and NPPs, spent fuel cycle facilities, radioactive waste management facilities,

activities in the scope: uranium mine, radiation sources in industrial and medical facilities,

emergency preparedness and response, transport and decommissioning

Organized by: International Atomic Energy Agency (IAEA)

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EXECUTIVE SUMMARY

At the request of the Government of the Czech Republic, an international team of senior safety experts met representatives of the State Office for Nuclear Safety (SÚJB) from 16 to 23 May 2017 to conduct the IRRS follow-up mission. The peer review took place at the headquarters of SÚJB in Prague. The purpose of the IRRS follow-up mission was to review the measures undertaken following the recommendations and suggestions of the 2013 IRRS Mission.

The review compared the Czech regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and their counterparts from the Czech Republic in the areas covered by the IRRS mission.

The IRRS team consisted of six senior regulatory experts from six IAEA Member States, four IAEA staff members and two observers.

The IRRS team carried out a review of the measures undertaken following the recommendations and suggestions of the 2013 IRRS mission in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection, enforcement, and the development and content of regulations and guides; emergency preparedness and response; safe transport of radioactive material; radioactive waste management and decommissioning; control of medical exposures; control of radioactive discharges and materials for clearance; environmental monitoring; occupational radiation protection.

The mission included interviews and discussions with SÚJB staff. The IRRS team was provided with advance reference material and comprehensive documentation including the status of the recommendations and suggestions set out in the initial IRRS mission report.

The IRRS team concluded that the recommendations and suggestions from the 2013 IRRS mission have been taken into account systematically, based on a comprehensive action plan. Significant progress has been made in all areas and many improvements have been implemented.

During this follow-up mission, the IRRS team determined that 16 out of 18 recommendations and 17 of 18 suggestions, made by the 2013 IRRS mission, have been effectively addressed and therefore could be considered closed. The IRRS team made the following general observations:

- The Government and the SÚJB have made considerable effort in establishing a new Atomic Act and 16 Decrees to address International Safety Standards. SÚJB continues to finalise the development of new regulations, guides and procedures, in line with the new legislation.
- Implementation of the new legislation, regulations, guides and procedures is a priority task for SÚJB
- SÚJB has established a project to further develop and implement its integrated management system, and has made progress in the development of its documentation. SÚJB needs to ensure availability of adequate resources for the completion of the project.
- The establishment of the Working Group on Medical Exposure has enhanced the collaboration between Ministry of Health, SÚJB and other involved parties, and has already lead to significant results, such as the revision of referral criteria.

• Significant progress was made by SÚJB in the areas of human resources management, inspections and enforcement.

The IRRS team identified a new good practice related to the active engagement of SÚJB in communicating with the public through a Web Conference.

The IRRS team raised a new suggestion to indicate where improvements are still necessary to continue enhancing the effectiveness of regulatory functions in line with the IAEA safety standards:

• SÚJB should consider developing regulations to detail and complement the general provisions in the Atomic Act on existing exposure situations and remedial activities;

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

I. INTRODUCTION

At the request of the Government of Czech Republic, an international team of senior nuclear and radiation safety experts met representatives of the State Office for Nuclear Safety (SÚJB) from 15 to 23 May 2017 to conduct the IRRS follow-up mission.

The initial IRRS mission took place from 18 to 29 November 2013 and an international team of senior experts in nuclear and radiation safety met representatives of SÚJB to review the Czech Republic regulatory framework for nuclear and radiation safety.

The purpose of the IRRS follow-up mission was to review the measures undertaken following the recommendations and suggestions of the 2013 IRRS Mission. The peer review took place at the headquarters of SÚJB in Prague. The review mission was formally requested in June 2014. A preparatory meeting was conducted during the period 29-30 November 2016 at the SÚJB office in Prague to discuss the purpose, objectives, scope and detailed preparations of the review.

The IRRS team consisted of 6 senior regulatory experts from 6 IAEA Member States, 4 IAEA staff members and two observers from Australia and the European Commission (EC).

The IRRS team carried out a review of the measures undertaken following the recommendations and suggestions of the 2013 IRRS missions in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection, enforcement, and the development and content of regulations and guides; emergency preparedness and response; safe transport of radioactive material; radioactive waste management and decommissioning; control of medical exposures; control of radioactive discharges and materials for clearance; environmental monitoring; and occupational radiation protection.

After the initial 2013 IRRS mission, an action plan was developed by SÚJB based on its findings. The detailed results of this action plan implementation and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews and discussions with SÚJB staff.

The findings by the IRRS team of 2013 that remain open can be found in Appendix IV.

The new IRRS team findings are summarized in Appendix V.

During the entire course of the preparation and the mission the IRRS team received excellent support and cooperation from the host institution.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS follow-up mission was to conduct a review of the Czech Republic radiation and nuclear safety regulatory framework and activities, specifically the measures undertaken following the recommendations and suggestions of the 2013 IRRS mission. The review was carried out by comparison of existing arrangements against the IAEA Safety Standards.

The IRRS review scope included all facilities and activities regulated by SÚJB.

It is expected that the IRRS mission will facilitate regulatory improvements in Czech Republic and other Member States from the knowledge gained and experiences shared by SÚJB, IRRS reviewers, and through the evaluation of the effectiveness of the Czech Republic nuclear and radiation regulatory framework and its good practices.

III. BASIS FOR REVIEW

A) Preparatory work and IAEA Review Team

At the request of the Government of the Czech Republic, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) follow-up mission was conducted from 29 to 30 November 2016 in Prague.

The preparatory meeting was carried out by the appointed Team Leader, Mr. Petteri Tiippana, and the IAEA representatives, Ms. Adriana Nicic and Mr Ibrahim Shadad. The Czech Republic team was led by the SÚJB Deputy Chairperson, Mr Petr Krs.

During the meeting, the representatives of the Czech Republic provided the IRRS mission preparatory team with an overview on the progress made in response to the 2013 IRRS mission recommendations and suggestions.

The preparatory meeting participants agreed that the scope of the follow-up mission will be the same as the 2013 IRRS mission. This was followed by a discussion on the work plan for the implementation of the IRRS follow-up mission in Czech Republic from 15 to 23 May 2017. The proposed IRRS team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer identification, lodging and transportation arrangements were also addressed.

The Czech Republic Liaison Officer for the preparatory meeting and the IRRS follow-up mission was Mr. Petr Krs, Deputy Chairperson of SÚJB.

SÚJB provided the IAEA and the IRRS team with the advance reference material for the review in March 2017. In preparation for the mission, the IRRS team conducted a review of the advance reference material and provided their initial review comments to the IAEA Team Coordinator prior to the commencement of the mission.

B) Reference for the review

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

C) Conduct of the review

An initial IRRS team meeting was conducted on Monday, 15 May 2017, in Prague by the IRRS Team Leader and the IAEA Team Coordinator to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. They also presented the agenda for the mission.

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

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

The IRRS entrance meeting was held on Tuesday, 16 May 2017, with the participation of senior management and staff of SÚJB. Opening remarks were made by Ms. Dana Drabova, the SÚJB Chairperson, and Mr Petteri Tiippana, IRRS Team Leader. Mr Petr Krs gave an overview of the major regulatory changes in nuclear and radiation safety since 2013 and presented the status of progress made regarding previous IRRS findings.

During the mission, a review was conducted for all the review areas with the objective of providing the Czech Republic with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, interviews and discussions.

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

The IRRS exit meeting was held on Tuesday 23 May 2017. The opening remarks at the exit meeting were presented by Ms Dana Drabova and were followed by the presentation of the results of the mission by the IRRS Team Leader, Mr Petteri Tiippana. Closing remarks were made by Mr Greg Rzentkowski, Director, Division of Nuclear Installation Safety.

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

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

R1

Recommendation: The Government should establish a national policy and strategy for safety to ensure that the Safety Fundamentals are explicitly adopted in a high level document.

Changes since the initial IRRS mission

Recommendation 1: In July, 2016 the Parliament of the Czech Republic adopted the new "Atomic Act" that entered into force on 1 January 2017 (No. 263/2016).

The IRRS team evaluated that the fundamental safety principles from the IAEA publication Safety Fundamentals SF-1 are included into the "Atomic Act". However, not all principles were explicitly included into the "Atomic Act" and the IRRS team was informed that this was not possible due to the national approaches. For example, it was discussed how the first principle about the prime responsibility for safety of the person or organization responsible for facilities and activities that give rise to radiation risks was incorporated into this Act. The IRRS team was informed that this principle was not implemented explicitly (using the same wording) from the SF-1 document. The IRRS team was of the opinion that the intent of the first principle is well met by the language used in the Act. In addition the IRRS team was informed that the final draft of the new Atomic Act passed the review by the legislative department of the European Commission before it was approved by the Parliament of the Czech Republic.

The IRRS team discussed the Chapter 3.1 "Nuclear Safety First (at the Top Level")" of the National Concept for Nuclear Energy Development that was approved by the Government on the 3rd of June 2014 that establishes the general strategy for nuclear safety for existing and future nuclear installations.

Status of the finding in the initial mission

Recommendation 1 (R1) is closed as the new "Atomic Act" entered into force on 1 January 2017 and contains all Safety Fundamentals principles relevant for the policy and strategy for safety.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

There were no findings in this area in the initial IRRS mission.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

There were no findings in this area in the initial IRRS mission.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

There were no findings in this area in the initial IRRS mission.

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

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

S1

Suggestion: The Government should consider establishing a national strategy for gaining or regaining control over orphan sources.

Changes since the initial IRRS mission

Suggestion 1: Paragraph 91 of the new "Atomic Act" provides for the operators of installations intended for melting, collecting or processing scrap metal to take measures for detecting any orphan sources. It requires operators to inform workers who can be exposed to ionising radiation from an orphan source on the effect of radiation. In addition, the operators should ensure that workers are able to visually recognize sources and to take actions in case of detection of orphan sources.

The provision also defines the responsibilities in cases if the orphan source detected inside or outside an installation intended for melting, collecting or processing scrap metal. In case of detecting an orphan source outside such an installation, the Radioactive Waste Repository Authority (SURAO) is responsible for collecting the sources and the Government becomes the source owner if the original owner is not identified.

SÚJB has issued new guidelines to the operators on detecting, collecting and seizure of radionuclide sources ("orphan sources") in the installations for melting, collecting and processing of scrap metal. New guidelines addresses the changes made in the legislation and have superseded the old guidelines. In addition, SÚJB distributed informative posters for scrap metal yard personnel providing instructions and describing the steps on how to deal with an orphan source in the first urgent phase.

The national strategy for security of radionuclides sources is disseminated through a specific document posted on the SÚJB website. The strategy describes responsibilities and steps to be taken also in the case and orphan source is found. It mainly makes reference to the paragraph 91 of the new Act.

The IRRS team was informed that SÚJB organises training events for metal recyclers and custom on dealing with orphan source if detected.

The IRRS team was informed that SÚJB has made preparation, in accordance with the provisions of the new "Atomic Act", to:

- recover and restore appropriate control over orphan sources;
- deal with radiological emergencies, and has established appropriate response plans and measures.

Status of the finding in the initial mission

Suggestion 1 (S1) is closed as the national strategy to gain and regain control over orphan sources is established.

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

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

Suggestion: The Government should consider adopting a process for periodic review of the document "Concept of Radioactive Waste and Spent Nuclear Fuel Management".

Changes since the initial IRRS mission

Suggestion 2: The requirements for periodically updating the Concept of Radioactive Waste and Spent Fuel Management (the Concept) were introduced into the new "Atomic Act". The Ministry of Economy and Trade is the responsible governmental body to organize and perform the periodic review of this document. According to the paragraph 108, Section 1 of the "Atomic Act" the Concept Radioactive Waste and Spent Fuel Management shall be regularly evaluated, no less than once every 10 years, and if necessary, updated.

The IRRS team was informed that final draft of the Concept has been issued by the Ministry of Industry and Trade taking into account the requirements of the EU Directive 2011/70/Euratom establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste. The issues related to the strategic environmental assessment will be incorporated into this Concept. SÚJB has been involved in the development of this document and officially commented its content. The IRRS team was informed also that all relevant comments of SÚJB were taken into account in the final draft of the Concept. The Governmental approval of this document is expected in July/August of 2017.

Status of the finding in the initial mission

Suggestion 2 (S2) is closed as the new Atomic Act establishes clear requirements for the periodic review of the Concept of Radioactive Waste and Spent Nuclear Fuel Management.

1.8. COMPETENCE FOR SAFETY

There were no findings in this area in the initial IRRS mission.

1.9. PROVISION OF TECHNICAL SERVICES

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

R2

Recommendation: In drafting amendments to the national regulatory framework, SÚJB should fully take into account IAEA Safety Standards and requirements.

Changes since the initial IRRS mission

Recommendation 2: Before commencing the process of revision and updating the "Atomic Act" SÚJB developed and approved the "Concept of New Atomic Act" based on the IAEA safety fundamentals, IAEA general safety requirements, EU Directives and national requirements for drafting the legislative documents. The purpose of the Concept was to ensure that all requirements in the aforementioned documents are taken into account in the process developing the Act. The "Atomic Act" was approved by the Parliament in July 2016 and entered into force in January 2017.

The IRRS team was informed that the procedure "Development of Registry for Compliance" (VDS 047) was established by the SÚJB as part of the integrated management system to perform periodic check of legal and regulatory documents for compliance with the IAEA safety standards, WENRA Reference Safety Levels and EU Directives. In addition, the IRRS team was informed that a software tool was created to support this activity. The IRRS team observed practical examples demonstrating the results of the "gap-analysis" based on the IAEA general safety requirements (IAEA GSR Parts 1 to 7) and relevant provisions of the EU Directives. SÚJB has also explained their approach for decision-making process and further steps to be taken if non-compliances are identified.

Status of the finding in the initial mission

Recommendation 2 (R2) is closed as the SÚJB has developed and implemented:

- a comprehensive approach for revision and updating of the "Atomic Act" taking into account IAEA general safety requirements and
- the procedure VDS 047 to check periodically the legal and regulatory documents for compliance with the IAEA safety standards, WENRA Reference Safety Levels and EU Directives.
- 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

S3

Suggestion: SÚJB should consider the development and implementation of a process for systematic review and evaluation of international events and the dissemination of relevant information, lessons learned and feedback on the measures undertaken.

Changes since the initial IRRS mission

Suggestion 3: The SÚJB developed and approved a procedure VDS021 "Activities of the nuclear safety and radiation protection inspectors during inspections of external feedback from operating experience acquired in the nuclear power plants". This procedure is part of SÚJB's integrated management system and describes the responsibilities and process how the international operational experience feedback (IOEF) is evaluated and taken into account during the planning and performing of inspection activities, including development of the inspection programs and implementation of the periodic inspections. Within the framework of these inspections, SÚJB inspectors verify licensees' processes in the IOEF area annually. The main information source for SÚJB and IOEF inspections is IAEA/NEA IRS and reports from the EC Clearinghouse.

The SÚJB has formalized communication with licensees on IOEF information. The IRRS team was provided with examples of SÚJB official letters addressed to the licensee ČEZ in 2016 and 2017 with requests to demonstrate how information provided by the EC Clearinghouse reports was taken into account by the ČEZ. Licensees' responses to SÚJB letters are used as inputs for inspections in the IOEF area.

In addition, the IRRS team was provided with a copy of the Inspection protocol prepared by SÚJB inspectors as result of planned inspection to verify how the licensee ČEZ had taken into account certain IRS reports. SÚJB also stated that findings from IOEF inspections are recorded in the SÚJB standard system used for tracking inspection findings. The IRRS team was informed that results of all SÚJB inspections are regularly discussed with licensee's management at various meetings (annual top level meetings, semi-annual meeting at each NPP site).

Negotiations with other national authorities and institutions responsible for oversight of safety have been initiated by SÚJB recently to provide a forum to exchange information and lessons learned related to the IOEF. The IRRS team was informed that the cooperation is in the beginning and SÚJB aims at creating an effective mechanism for cooperation with other authorities and institutions in the IOEF area.

Status of the finding in the initial mission

Suggestion 3 (S3) is closed as SÚJB has established and implemented a process addressing the international operational experience feedback and described it in the procedure VDS 021.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

There were no findings in this area in the initial IRRS mission.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

There were no findings in this area in the initial IRRS mission.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

- **Recommendation:** SÚJB should define a long term strategy for human resource development including corporate knowledge management as needed to ensure the accomplishment of key regulatory functions in the future.
- Suggestion: SÚJB should consider formally define core technical competences in all areas of its activities and ensure that these are represented in the available staff in order to properly discharge its regulatory responsibilities.
- Suggestion: SÚJB should consider introducing a process for feedback from the trainees as a mandatory step for improvement of the systematic approach to training process and quality assurance principles to training.

Changes since the initial IRRS mission

Recommendation 3: At the end of 2016, SÚJB developed a new IMS document (VDK 097) - "The Long-Term Strategy for Development of Human Resources" (the Strategy). The aim of the Strategy is to contribute to the provision of long-term development of human resources for continual qualified execution of public administration, including inspection and supervision, in the use of nuclear energy and ionizing radiation and non-proliferation of weapons of mass destruction. Strategy documents (VDK) are new type of IMS documents introduced to the SÚJB management system through the new IMS Manual (2015).

Eleven strategic principles, to which SÚJB wants to adhere in its human resources development efforts in the mid-term horizon, are the pillars of this document. These principles address aspects related to the long-term development of human resources based on the SÚJB competence needs, integrated management of the resources at the SÚJB level, required levels of competencies in SÚJB, planning of the human resources development based on three years projection, educational activities, feedback from trainees after training sessions, training of the inspector assistants, civil servant exams and rotation of employees, replacement of employees and knowledge management, objectivity of the SÚJB employees decisions, recruitment and training of personnel filling the vacant positions, sufficient qualification to evaluate quality and results of external technical assistance. The principles are drawn from IAEA standards relevant for this area (GSR, GS-R, GS-G, TEC-DOCs). The knowledge management is included in the principles as one of the cornerstones of the human resources strategy.

The IRRS team was informed that a three years action plan is developed for the practical implementation of the Strategy and it is annually reviewed and updated as necessary.

Suggestion 4: A methodological instruction (VDI 098) – "Processing the competency map" was introduced by SÚJB in order to support the implementation of the 11 strategic principles from VDK 097. The methodical instruction shall guide the process of developing competency maps within SÚJB.

The IRRS team was informed that the competences map for the Radiation Protection Section and Non-proliferation Department have been already completed, while the process for mapping the technical competencies of the Nuclear Safety Section staff was under implementation.

Other organizational departments (sections) have started competency mapping with the aim to inform and support financial planning for 2018-2021(deadline is end of July 2017).

Suggestion 5: The IRRS team was informed that the revised version of SÚJB IMS procedure (VDS039) – "System of preparation, education and evaluation of the SÚJB's workers" implements the relevant provisions of the new Civil Service Act. VDS039 was approved by the SÚJB Chairperson in the December 2016.

The VDS039 includes new provisions on systematic collection and use of feedback from trainees during training sessions organized by SÚJB. Forms for collecting feedback from trainees are included in the appendix of VDS039.

Although not in the scope of the original suggestion, the IRRS team sees further potential for improvement of the training process, if SÚJB would systematically analyse feedback also from external trainings.

Status of the finding in the initial mission

Recommendation 3 (R3) is closed as SÚJB has developed the document "The long-term strategy for development of human resources" that will be implemented according to the three year action plan.

Suggestion 4 (S4) is closed on the basis of progress made and confidence in the effective completion as SÚJB has already completed the competencies map for the Radiation Protection Section and mapping of the technical competencies for the Nuclear Safety Section is under implementation.

Suggestion 5 (S5) is closed as SÚJB has established new provisions (IMS procedure VDS039) on systematic collection and use of feedback from trainees during the training sessions.

3.4 LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

R4

Recommendation: It is recommended that a specific procedure is developed, identifying the rules to manage the selection process of TSOs and the monitoring of their work, to ensure that potential conflicts of interest do not compromise the reliability of the received advice.

Changes since the initial IRRS mission

Recommendation 4: At the beginning of 2017, SÚJB issued the Order on the Management & Technical Support Section Director No. 1/2017 to Prevent Any Conflict of Interests in Providing

the Specialised Technical Support (the Order). The Order describes the rules for selection, contracting, monitoring and accepting the external advice and provides all necessary conditions to which the applicant should comply with in order to avoid the potential conflict of interests. The intention of SÚJB is to convert this Order into an IMS document.

In accordance with the selection rules, established in the Order, it is expected that:

- Those who participated in development of any licensees' submissions to SÚJB cannot afterwards provide external expert advice to SÚJB;
- Contractors (individuals/teams/organizations) that provide external expert advice to SÚJB can enter in any contract/communication with license applicants/holders only after written consent of SÚJB;
- Contracts should contain lists of experts and their independence and competence must be proved;
- Subcontracts should be approved by SÚJB.

The SÚJB assignee (responsible staff) is obliged to monitor the activity of external experts continuously during the duration of a contract. Where appropriate, the contractor should develop a work plan that includes method and schedule (incl. hold points) for execution of contracted activities, each phase (where appropriate) must be formally accepted, and ways for documenting specific part of process and its outputs for each phase have to be defined.

Status of the finding in the initial mission

Recommendation 4 (R4) is closed as SÚJB issued and implemented an order that provides the rules for avoiding potential conflict of interest during selection and contracting of external advice.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There were no findings in this area in the initial IRRS mission.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

There were no findings in this area in the initial IRRS mission.

3.7. SAFETY RELATED RECORDS

There were no findings in this area in the initial IRRS mission.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

There were no findings in this area in the initial IRRS mission.

4.2. MANAGEMENT RESPONSIBILITY

There were no findings in this area in the initial IRRS mission.

4.3. RESOURCE MANAGEMENT

There were no findings in this area in the initial IRRS mission.

4.4. PROCESS IMPLEMENTATION

There were no findings in this area in the initial IRRS mission.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

Recommendation: SÚJB should further develop and implement its Integrated Management System for satisfying fully the requirements set out in IAEA safety standards and guides with regard to:

- a) process implementation;
- **R5** b) promotion of safety culture;
 - c) measurement, assessment and improvement;
 - d) management of organizational changes;
 - e) application of graded approach

Changes since the initial IRRS mission

Recommendation 5: SÚJB is using in its operational activities the existing management system procedures, as well as those that have been revised or issued since 2013. The further development and implementation of the Integrated Management System (IMS) was initiated after the 2013 IRRS mission and was organised by SÚJB as a two-phase project: during the first phase (09/2014 to 10/2016) the basic framework, including the IMS Strategy Statement and a new IMS Manual (SÚJB Process Model) were developed. The IMS manual contains the principles relevant to the IMS of the SÚJB, in a number of areas, including: organization, safety management, objectives management, process management documentation management, management of compliance with standards and updating the management manual. These principles will guide the further development and revision of the supporting IMS documents.

In the initial phase of the project, an external audit, including a survey, was conducted to identify gaps in the existing IMS and its results were analysed by SÚJB managers in order to establish priorities for enhancements of the IMS. The main priorities that were identified are related to: concepts and strategies; development and formalization of the management system/ manual; grading of processes; process management; and compliance management.

SÚJB (VDS 028) that is used for guiding the process for the development of all organizational standards (these include VDK, VDS and VDI documents/ procedures) developed by the regulatory body. The graded approach to be applied in the development of SÚJB organizational standards is documented. This includes three types of documents and three levels for VDS and VDI procedures, which may be applicable to the whole organization, at a section level or at an organizational unit level. In addition, a report was prepared, introducing grading of processes (based on ISO/IEC 15504) in five levels of processes, based on the maturity level. The IRRS team was presented with examples of new procedures in which this approach was applied. The use of performance indicators is specified for certain levels of procedures.

A number of organizational standards/ procedures have been revised or developed since 2013. Most of the revised/ new developed procedures are in the areas of Governance and Management. The IRRS team noted that SÚJB is planning to develop procedures for safety culture, formalising the existing practices and for management of change, including organizational changes. Consideration is also given to the development of a documented process/ procedure for knowledge management, but no decision has been taken yet.

Currently there is no overall representation of the coverage and link between the management system requirements (GS-R-3) relevant to for the IMS manual, the main regulatory processes and the set of existing organizational standards/ procedures (around 100 documents). The IRRS team advised SÚJB to develop such a road map, integrating all the elements of the IMS in order to have a clear picture of the desired output of this project. Taken into consideration that the IMS manual makes currently reference to GS-R-3, which was superseded recently by GSR Part 2, Leadership and Management for Safety, it is suggested that SÚJB should consider aligning its management system with the new IAEA safety standard.

The IRRS team was informed that the ownership for this project resides with the highest level of SÚJB's management and the main participants are the three section heads and head of the department for Emergency Management. Currently there are two SÚJB dedicated staff members working on this project and the project befits also from external support.

The IRRS team was informed that phase 2 of the development of the IMS is planned to be completed by 2020 and that the necessary resources have been planned accordingly.

The long duration for the implementation of this project was discussed and the IRRS team was informed that SÚJB made a decision that the IMS will be developed mostly by SÚJB experts. The same experts are needed for addressing a number of priorities, including the revision and development of the new legislative and regulatory framework, as well as operational activities (e.g. periodic safety reviews at nuclear facilities).

Status of the finding in the initial mission

Recommendation 5 (R5) is open as SÚJB has not fully completed the development and implementation of its Integrated Management System. This project is planned to be completed by 2020.

5. AUTHORIZATION

5.1. GENERIC ISSUES

There were no findings in this area in the initial IRRS mission.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

	2013 MISSION RECOMMENDATIONS, SUGGESTIONS
S 6	Suggestion: SÚJB should consider developing provisions for the effective coordination with other relevant authorities having responsibilities within the authorization process of nuclear installations.
R6	Recommendation: SÚJB should review and revise the decree covering the design requirements for NPPs to ensure that the design requirements take into consideration the IAEA safety standard SSR-2/1 "Safety of Nuclear Power Plant Design".
S7	Suggestion: SÚJB should consider developing further the internal guidance on authorization of nuclear installations to cover all stages specified in the Atomic Act well in advance of these stages.

Changes since the initial IRRS mission

Suggestion 6: SÚJB assessed the need to develop provisions for effective coordination with the other relevant authorities, and they concluded that general provisions for the coordination between different state authorities are adequately provided by the State Administrative Procedure Act.

For the authorization of nuclear installations in the environmental impact assessment phase, the responsibility for coordination is given to the Ministry for Environment by Act No. 100/2001 Coll. on Environmental Impact Assessment; for the phases of siting, construction, operation and decommissioning the responsibility for coordination is given to the Civil Construction Authority by Act No. 183/2006 Coll. on Spatial Planning and Building Rules (the Building Code).

As an example, the construction permit for Service Water Cooling Towers issued by the Civil Construction Authority was presented to the IRRS team to demonstrate how the positions of the other authorities involved in the assessment process were taken into account.

Recommendation 6: A new Decree "Requirements to Design of Nuclear Installation" based on the IAEA Safety Standard SSR 2/1 "Safety of Nuclear Power Plant Design" has been prepared. The implementing decree is in the final stage of preparation, and awaits approval by the Legal Governmental Committee. The decree is issued as an explanatory rule to the new Atomic Act.

A comparative table demonstrating how the decree complies with IAEA SSR 2/1 was presented to the IRRS team. The majority of requirements are fully addressed by the new Decree. For requirements not fully covered by the new Decree, a regulatory guide will be developed.

Suggestion 7: The new IMS procedure VDS 104 describing different stages of authorization of nuclear installations was developed and refers to subsequent internal guidance. The procedure covers authorization processes which are being implemented at the moment – operation and modifications and describes at the general level the basic review and assessment activities and

provides an overview of the internal documents which describe review and assessment activities in more detail.

Detailed internal guidance for authorization of siting, construction or decommissioning of a nuclear installation is, according to the procedure, required to be prepared in advance, approximately one year before the planned activity.

Status of the finding in the initial mission

Suggestion 6 (S6) is closed as provisions for coordination between different state authorities are given by the State Administrative Procedure Act.

Recommendation 6 (R6) is closed as the new decree "Requirements to Design of Nuclear Installation" based on the IAEA Safety Standard SSR 2/1 "Safety of Nuclear Power Plant Design" is in the final stage of preparation.

Suggestion 7 (S7) is closed on the basis of progress made and confidence in effective completion as the new IMS procedure VDS 104 describing different stages of authorization of nuclear installations was developed. VDS 104 requires further internal guidance for authorization of currently missing phases (e.g. siting, decommissioning) to be developed well in advance of the planned activity.

5.3. AUTHORIZATION OF RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

S8

Suggestion: SÚJB should consider the arrangements necessary, in isolation or in parallel with the government, for the development of independent research and assessments for the disposal of spent nuclear fuel.

Changes since the initial IRRS mission

Suggestion 8: SÚJB has launched its own research project in order to build up its capabilities to regulate and evaluate the safety of a deep geological repository (DGR) in Czech Republic. A first contract for a two-year independent research project was signed in 2015 with Research Center Rez (CVR). This project is expected to be finalized by the end of 2017. The expected outputs of this project are:

- assessment of the source term of DGR (SF, RAW);
- initial mathematical model of basic components of DGR GW transport and biospherical model, model of engineered barriers, heat transfer model;
- analysis of available input data and sensitivity analysis;
- comparison of disposal concepts;
- recommendations for mining technologies and for geotechnical monitoring of DGR;
- database of input parameters, etc.

The project output is mainly designed to increase the competency of SÚJB staff in the long term for the evaluation of the initial SAR for a DGR.

A new TSO for nuclear safety is being created under the umbrella of SÚRO (National Radiation Protection Institute). The SÚRO strategy for 2018 - 2020 was presented to the IRRS team. This strategy also covers spent fuel and radioactive waste management. The expected next steps in the research programme include research in the area of long-term behaviour of nuclear fuel cladding.

The continuation of the research activities is intended, in accordance with the national strategy. SÚJB's 3-year financial plan takes into account research activities related to DGR.

The Radioactive Waste Repository Authority (SURAO) is responsible for the development of a DGR. This governmental agency is conducting and coordinating numerous research and demonstration projects with the goal of gathering information on the feasibility of the disposal facility and its long-term behaviour. A memorandum of understanding for the cooperation between SÚJB and SURAO was signed in 2014.

Status of the finding in the initial mission

Suggestion 8 (S8) is closed on the basis of progress made and confidence in effective completion as a first independent research project is ongoing and further activities are planned to increase the competency of SÚJB staff to regulate the DGR.

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES

There were no findings in this area in the initial IRRS mission.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

5.7. AUTHORIZATION OF TRANSPORT ACTIVITIES

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

There were no findings in this area in the initial IRRS mission.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

	2013 MISSION RECOMMENDATIONS, SUGGESTIONS
S9	Suggestion: SÚJB should consider documenting systematically the reasons that lead to rejecting or endorsing a recommendation of technical support organisations.
S10	Suggestion: SÚJB should consider developing further their use of expert advice to include technical support organisation from the international community.
S11	Suggestion: SÚJB should consider regularly, independently and comprehensively assessing the probabilistic safety analyses for nuclear power plants.
S12	Suggestion: SÚJB should consider increasing the coverage of safety relevant issues by regulatory guides complementary to regulations to provide quantitative criteria to allow for the assessment of all items important for nuclear safety.
R7	Recommendation: SÚJB should develop binding regulation requiring the licensee to perform a periodic safety review of nuclear installations.

Changes since the initial IRRS mission

Suggestion 9: SÚJB issued a new procedure – (VDS 106) "Rules concerning the assessment of TSO's recommendations" which formally describes the process of internal review and acceptance of recommendations proposed by technical support organizations (TSO).

The assessment of the TSO recommendation is done in terms of Proportionality, Accountability, Consistency, Transparency, Targeting and Direction.

The approval level of the TSO's recommendation is based on a graded approach, being determined by the one of following categories:

- Category A (high)
- Category B (middle)
- Category C (low)

The decision for the highest category of the recommendation is taken by the Management Board (Executive Meeting) which consists of the Chairperson, the Director for Nuclear Safety, the Director for Radiation Protection, the Director for Management and Technical Support and the Director for Crisis Management and Informatics, while the decision for the lowest category of recommendation is taken by the Director of the respective Department.

The output of the assessment process may consist of one of the following decisions:

- Adoption of the recommendation with or without modification;
- Temporary postponement of the recommendation until further assessment or follow-up actions;
- Rejection of the recommendation.

Suggestion 10: The SÚJB has informed the IRRS team that use of technical support from abroad, as well as for obtaining knowledge at the highest professional levels is a current practice of SÚJB for many years. There are no administrative or financial limitations for SÚJB in using foreign expertise. In the last five years, SÚJB returned approx. 2 million Euro to the state budget annually, mainly from the budget for acquiring technical support.

Up to now, the SÚJB has turned to organizations which have direct experience with VVER type reactors (Slovakia, Hungary, Russian Federation, Ukraine). In cases of other technologies used in Czech nuclear installations (for example digital I&C or nuclear fuel from Westinghouse), SÚJB cooperated directly or through its TSOs with expert organizations from the countries of origin – USA, France, Russian Federation, etc. SÚJB have had contracts with foreign TSOs such as ENCONET from Austria (training of SÚJB staff in the use of PSA) in the past or VÚJE from Slovakia.

Suggestion 11: The Government of the Czech Republic and the SÚJB included in the new Atomic Act requirements for the use of PSA in different phases of NPP authorization. The IMS procedure VDMI 093 "Guide on independent PSA review" that formally describes the methodology for internal (SÚJB) independent PSA assessment was revised to cover comprehensive assessment by external experts. This procedure takes into account available expertise in SÚJB, the expertise that might be available in the future in the newly established internal TSO for nuclear safety, and the availability of other independent external expert advice.

SÚJB elaborated the document "Strategy and action plan of PSA on SÚJB". This document also provides a section dealing with the issue of independent assessment of PSA stating that independent assessment of PSA can achieved in different ways. A comprehensive assessment of the PSA can be carried out by:

- 1) the IAEA mission (TSR) based on an invitation from SÚJB (SÚJB is aware that this is not a complete substitute for own independent evaluation of the PSA suggested by the IRRS mission, since this type of mission is performing only a limited review of the PSA study)
- 2) independent organizations (commercial contracts) or
- 3) the SÚJB staff themselves, who can be supported by independent support organizations or independent experts.

The SÚJB is of the opinion that the appropriate approach for the implementation of the IRRS suggestion is to apply options 2) and 3).

Since the full scope PSA update for Dukovany NPP has been completed at the end of 2015, SÚJB decided to start an independent and comprehensive assessment of this PSA. SÚJB recognized that given the extensiveness of the PSA, this assessment cannot be actioned immediately and at the same time for the whole PSA in all its aspects. As a first step for independent assessment of the existing PSA, SÚJB has chosen to invite the IAEA Technical Safety Review (TSR, previously IPSART, IPERS) mission on the PSA for the Dukovany NPP in

the year 2016. A similar approach will be followed for the Temelin NPP once the updated PSA study will be provided to SUJB.

Progress has been made in response to the IAEA IRRS mission suggestion. SÚJB is planning to place contracts for the implementation of the independent and comprehensive assessment of PSAs. The goal of the assessment is to gain confidence that the PSA has been carried out to an acceptable standard so that it can be used as the basis for taking risk informed decisions within a regulatory decision making process.

The first contract for an independent assessment on selected parts of the PSA (data analysis) is being prepared. The work will start in 2017. The IRRS team noted that the SÚJB schedule for the comprehensive assessment of the entire PSA study is 10 years since licensee submission. This duration is not compatible with the purpose of the PSA study (e.g. use of PSA to support safe and efficient operation of the plant) nor with the legal requirements imposed by the Atomic Act on the licensee for delivering updates of the PSA study at every 5 years. The completion of the regulatory independent assessment should adjusted to the licensee's submittals and with the international practice (e.g. IAEA Safety Series No.50-P-4, IAEA Safety Series No.50-P-8), as well as with approaches taken by other regulatory bodies.

The IRRS team would like to highlight also that currently there is only one PSA expert in SÚJB and no PSA review capability in the in the newly established TSO.

In accordance with the GSR Part 1, para. 4.22 requirements, the obtaining of external technical advice and assistance does not relieve the regulatory body of its assigned responsibilities. The regulatory body shall have an adequate core competence to make informed decisions. In making decisions, the regulatory body shall have the necessary means to assess advice provided by advisory bodies and information submitted by authorized parties and applicants.

Suggestion 12: Since 2013, the SÚJB concentrated their effort in the development of the new implementing Decrees needed to supplement the new Atomic Act. These decrees provide in most cases the quantitative criteria which were included in guidance documents in the past. This is a result of a new legislative approach adopted by the Government.

The development of guidance was slightly slowed in 2013-2016, the effort being put in drafting new legislation.

In accordance with the Nuclear Safety Section Director Order No. 2/2017 the revision of all SÚJB regulatory guides in nuclear safety area is planned for 2017 – 2018. About 31 regulatory guides will be available at the end of this process, covering all aspects relevant for the achievement of an adequate level of nuclear safety, and will provide quantitative criteria, where appropriate.

The IRRS team was informed that there were no guidance documents issued in the last three years but the work for drafting the documents has started and will be competed once all the new Decrees that implement the Atomic Act will be issued. An IMS Procedure (VDS 027) for development of SÚJB guides was revised in 2016.

Recommendation 7: The Government of the Czech Republic and SÚJB has set the legal binding requirements for Periodic Safety Review process in the following legal documents:

- The new Atomic Act (Act No. 263/2016 Coll., in force since 1.1.2017) para 48 (Safety Assessment), section 2 c) Periodic Safety Review: "Periodic Safety Review must be included in Safety Assessment of a Nuclear Installation"
- The new Decree on Safety Assessment Requirements (recently passed through the Legislative Council)

The Decree includes detailed provisions on PSR process regarding its scope, period, deadlines, and documentation and it was developed in line with IAEA SSG-25 (NPPs) and draft IAEA publication on periodic safety review for research reactors.

Status of the finding in the initial mission

Suggestion 9 (S9) is closed as SÚJB has established and documented a process for internal review and acceptance of recommendations proposed by technical support organizations (TSO).

Suggestion 10 (S10) is closed as SÚJB has provided additional information on their use of technical support from the international community.

Suggestion 11 (S11) is open as SÚJB has not yet developed adequate resources to regularly, independently and comprehensively assess probabilistic safety analyses for nuclear power plants.

Suggestion 12 (S12) is closed on the basis of progress made and confidence in the effective completion as SÚJB has started drafting the regulatory guides and will continue in accordance with the SÚJB internal order.

Recommendation 7 (R7) is closed as binding requirements for periodic safety review of nuclear installations were included in the Czech nuclear legislation.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

S13

Suggestion: SÚJB should consider preparing regulatory criteria for the safety of research reactors in extended shutdown.

Changes since the initial IRRS mission

Suggestion 13: The Government of the Czech Republic and SÚJB included in the new Atomic Act (para 54 (4) b) and c)) and in the implementing Decree (Decree No. 21/2017 Coll. on Ensuring of Nuclear Safety) specific requirements for the extended shutdown of research reactors.

Requirements stipulated by Decree No. 21/2017 Coll. (on Ensuring of Nuclear Safety) takes into account a planned (e.g. caused by financial reasons) as well as an unplanned (e.g. caused by technical reasons) extended shutdown of a research reactor.

The IAEA NS-R-4 Safety of Research Reactors was used as the main basis for the requirements.

Status of the finding in the initial mission

Suggestion 13 (S13) is closed as SÚJB has established the regulatory criteria for the safety of research reactors in extended shutdown.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT AND FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

7. INSPECTION

7.1. GENERIC ISSUES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

S14

Suggestion: SÚJB should consider verifying that the inspection programme and related inspector training for nuclear facilities address the applicable inspection areas and aspects for each stage of the authorization process delineated in GS-G 1.3.

Changes since the initial IRRS mission

Suggestion 14: The SÚJB inspection program VDS 008 is developed based on GS-G-1.3 with the aim of covering all applicable inspection areas in each stage of the authorization process.

Based on the suggestion, the inspection program was reviewed by SÚJB. Based on this review, inspection procedures for the operation phase of nuclear installations that were not available during the initial IRRS mission were identified, developed and issued.

For the other lifetime phases of nuclear facilities, inspection procedures will be prepared in accordance with SÚJB Core Inspection Program VDS008 well before the start of these stages, e.g. inspection procedures for siting, construction or decommissioning.

The IRRS team was informed that, once the road map for a new nuclear installation is available, SÚJB will start a revision of the inspection programme to issue needed inspection procedures well in advance.

Since the initial IRRS mission in 2013 the following inspection procedures have been developed and issued:

- VDS021 on inspections of external OEF;
- VDS066 on inspections of NSSS status:
- VDS068 on inspection of auxiliary systems status;
- VDS073 and VDS 082 on inspections of staff qualification;
- VDS075 on inspections focused on quality of PSA models;
- VDS076 on inspections of industrial safety aspects at NPPs;
- VDS077 on inspections of licensee contractors:

The IRRS team was informed that any supervisor has the responsibility to provide for training of his staff - in this case on the inspection procedure VDS008 on planning, execution and evaluation of inspection activities of nuclear installations. Examples of corresponding training records of a supervisor and an inspector were provided (including training needs, training plan, and training records). For new inspection procedures, no specific training was organised. SÚJB considers that specific training is not needed since inspectors conducting the inspections have been drafting the new inspection procedures.

Status of the finding in the initial mission

Suggestion 14 (S14) is closed on the basis of progress made and confidence in effective completion as new inspection procedures have been issued to address applicable inspection

areas to cover the operational stage of the authorization process. For the other stages of the lifetime of nuclear facilities, inspection procedures will be prepared in advance in accordance with SÚJB inspection procedure VDS008.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

There were no findings in this area in the initial IRRS mission.

7.3. INSPECTION OF RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

7.4. INSPECTION OF FUEL CYCLE AND WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES

There were no findings in this area in the initial IRRS mission.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

7.7. INSPECTION OF TRANSPORT ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

S15

Suggestion: SÚJB should consider more comprehensive and frequent training for regional inspectors undertaking inspections of the transport of radioactive material.

Changes since the initial IRRS mission

Suggestion 15: For the systematic training of SÚJB employees, the procedure VDS 039 was developed. This procedure defines how the scope and frequency of training of employees is determined and executed. The training of regional inspectors is also based on this procedure.

A training plan for the period 2016 - 2018 for four regional inspectors was presented to the IRRS team as an example.

For the regional inspectors three training events on transportation of radioactive material were held during the years 2015 and 2017. The IRRS team was informed that these trainings covered the new national legal framework of transport of radioactive and fissile material, the significant changes concerning the transport of radioactive material according to the new act No. 263/2016 Coll. and according to the implementing legal regulation, the new Decree No. 379/2016 Coll. Concerning the Approval of Some Products in the Field of Peaceful Use of Nuclear Energy and Ionising Radiation and the Carriage of Radioactive or Fissile Material.

Status of the finding in the initial mission

Suggestion 15 (S15) is closed as the training of regional inspectors is covered by the internal procedure VDS039 for the systematic education of SÚJB personnel (defining scope and frequency of training), and as three training events on transportation of radioactive material were held since 2015.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

	2013 MISSION RECOMMENDATIONS, SUGGESTIONS
R8	Recommendation: SÚJB should finalize efforts to revise the Atomic Act to provide a detailed scale of penalties for nonconformities commensurate with their severity.
R9	Recommendation: SÚJB should establish and implement a comprehensive enforcement policy that takes into account all regulated activities, existing legal requirements and internal documents.

Changes since the initial IRRS mission

Recommendation 8: In the new Atomic Act, prescriptive approach in imposing penalties is introduced in a dedicated chapter.

The progress in the Atomic Act is significant compared to the previous Act, the process for imposing penalties is more prescriptive, comprehensive, transparent and reflecting nature and seriousness of the issue.

A detailed scale of penalties as well as a categorization of nonconformities according to subjects, types of authorization and according to type of activity is developed.

Based on the Atomic Act the amount of the fine depends on the severity of nonconformity.

Recommendation 9: An enforcement policy has been developed and issued. This document (VDK 095) includes enforcement objectives, general principles that are common to all enforcement tools, and required staff qualifications.

The policy describes in general the principles for using enforcement tools in the inspection process (penalties, reporting, and binding instructions), the enforcement instruments within the administrative procedure, the amendment or withdrawal of an authorisation, and remedial measures and penalties.

The IRRS team was shown a training plan that was based on the requirements for qualification of staff for enforcement activities, in line with the internal procedure VDS039 for training of SÚJB staff.

Status of the finding in the initial mission

Recommendation 8 (R8) is closed as the new Atomic Act provides a detailed scale of penalties corresponding with their severity.

Recommendation 9 (R9) is closed as an enforcement policy was issued and implemented.

8.2. ENFORCEMENT IMPLEMENTATIONS

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

R11

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

Recommendation: The Government should ensure a top-down approach is used for issuing regulatory requirements and guides. This may be achieved by ensuring the revised Act will contain all the necessary provisions for allowing SÚJB to develop regulatory requirements for all areas of nuclear and radiation safety for medicar facilities.

nuclear facilities.

Recommendation: SÚJB should have a formalized procedure to undertake a gap analysis between new IAEA requirements and the Czech legislative framework in order to draft revisions to the legislative framework to keep legislation up to date. SÚJB should develop a process for reviewing and updating regulations and guides systematically. Especially new developed IAEA requirements should systematically be checked and if appropriate adopted into the Czech legislative framework.

Changes since the initial IRRS mission

Recommendation 10: The IRRS team found that the Government of the Czech Republic and SÚJB addressed the recommendation in a systematic way.

The Atomic Act contains the necessary provisions for allowing SÚJB to develop regulatory requirements (Decrees or Governmental Orders) for all areas of nuclear safety as well as radiation safety – essentially defined in paras. 236 and 237.

The Legislative Rules of the Government are – with respect to the issue - clear and they precisely define which provisions shall be codified at which level - through an act of the Parliament or through the secondary legislation level (Governmental Orders, Decrees). They also define precisely how the aforementioned authorizations shall be formulated.

The IRRS team found that the Atomic Act contains all necessary authorizations for SÚJB to issue Decrees that will contain the necessary detailed criteria for the safe use of nuclear energy and ionizing radiation needed for effective regulation.

Recommendation 11: The IRRS team found that SÚJB addressed and resolved the recommendation in a systematic way.

The procedure "Development of the Registry of Compliance" (VDS047) for compliance management was developed as principal SÚJB IMS document and is ready to be implemented. This procedure will be used for conducting a gap analysis between newly issued IAEA requirements and the Czech legislative framework. The procedure guides the process of identification of international standards which SÚJB intends to mirror in its nuclear legislation and the subsequent processes of comparison with the Atomic Act, implementing Decrees, and (if considered appropriate) Regulatory Guides, identification of the need for revision of documents and the triggering of the actual document development.

The described process is just starting to be implemented. With the Atomic Act and the corresponding decrees a good baseline for the future has been set.

The baseline for the "management of compliance" between IAEA and Czech nuclear legislation is "compliance tables" containing detailed mapping of IAEA, EU and WENRA requirements to Czech national requirements that have been prepared and that will be kept up-to-date by "guarantors" - experts within SÚJB responsible for drafting different pieces of nuclear legislation.

Both the procedure VDS047 and first examples of "compliance tables" and "compliance statements" were reviewed and extensively discussed during the IRRS follow up.

Status of the finding in the initial mission

Recommendation 10 (R10) is closed as the Atomic Act contains the necessary provisions for SÚJB to issue implementing Decrees that will contain the detailed criteria for the safe use of nuclear energy and ionizing radiation needed for effective regulation.

Recommendation 11 (R11) is closed as with the Atomic Act and the corresponding decrees a baseline has been set and with the procedure VDS047 and the "compliance tables" a procedure exists for conducting a formalized gap analysis and for identification of the necessary actions (revisions etc.) in the future.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

There were no findings in this area in the initial IRRS mission.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

R12

Recommendation: SÚJB should require comprehensive and systematic consideration of human factors at the early stage of the design process of the nuclear facilities and when modifying relevant SSCs.

Changes since the initial IRRS mission

Recommendation 12: The IRRS team found that SÚJB has developed a new "Decree on Requirements on Design of Nuclear Installations". This Decree is in the final stages of being issued and is applicable to all nuclear installations.

The IRRS team reviewed and discussed this Decree extensively during the mission with the counterparts. The Decree contains requirements for comprehensive and systematic consideration of human factors early in the process of receiving a license for nuclear installations. Relevant provisions are included as

- a generic requirement in para. 4 (1) e) demanding "the consideration of the influence of human performance" as well as
- a requirement in para. 41 (3) a) especially for the control room demanding "to take into account the human factor and ergonomic user interface for control room staff.".

Thus, the necessary requirements for consideration of human factors in design or modification processes of nuclear facilities have been introduced.

Status of the finding in the initial mission

Recommendation 12 (R12) is closed based on the fact that of the new "Decree on Requirements on Design of Nuclear Installations" contains the necessary requirements for consideration of human factors in design or modification processes of the nuclear facilities.

9.4. REGULATIONS AND GUIDES FOR FUEL CYCLE AND WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

9.5 REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITES

There were no findings in this area in the initial IRRS mission.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

R13

Recommendation: SÚJB should include in its licensing scheme a method for restricted or unrestricted release of the land, buildings and structures from further regulatory control. Regulatory criteria and procedures for restricted or unrestricted release of the land, buildings and structures from further regulatory control should also be provided.

Changes since the initial IRRS mission

Recommendation 13: The new Atomic Act clearly stipulates in Paragraph 9, Section 7 that: "A license issued by the Office is required for complete decommissioning".

During the review the relevant terms were explained to the IRRS team in the context of Czech legal rules.

The term "complete decommissioning" (covering the contents of the IAEA term "final release") is defined in the Act in Paragraph 3, Section 2, letter f) as follows: "Complete decommissioning means to bring the nuclear facility or category III. or IV. workplace to the condition which allows its unrestricted utilisation for another purpose or to use the site, where it has been placed, for unrestricted use."

For restricted release, the Decree No. 377/2016 Coll. on Requirements on RAW Management and on Decommissioning of Nuclear Facilities or Category III. or IV. Workplaces stipulates in paragraph 12 section 1 that: "If the area in which a nuclear installation or a category III or IV workplace is placed and systems, structures, or components of these facilities cannot be made available for use without restriction, the licensee for decommissioning shall assess their long-term safety and the licensee shall then implement appropriate measures to ensure them."

If a complete decommissioning is not performed, the future licensee has to define conditions for further use of the site and SSCs including the scope and methods of surveillance, measurements, assessments, verification and recording of parameters and facts important from the point of view of radiation protection and monitoring of the radiation situation.

Relevant radiological criteria (e.g. for the baseline survey and for the decision on the final release from supervision) are listed in the annexes of the Decree No. 360/2016, on Radiation Situation Monitoring".

During the review the aforementioned documents were reviewed and discussed by the IRRS team.

Status of the finding in the initial mission

Recommendation 13 (R13) is closed based on the fact that a licensing scheme for restricted or unrestricted release is contained in the new Atomic Act and the Decree No. 377/2016 Coll. on Requirements on RAW Management and on Decommissioning of Nuclear Facilities or Category III. or IV. Workplaces.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

There were no findings in this area in the initial IRRS mission.

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. GENERAL REQUIREMENTS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

R14

Recommendation: The Government should ensure that threat categorization, national emergency plan and recovery actions in the Czech legislation will be in line with GS-R-2 requirements.

Changes since the initial IRRS mission

Recommendation 14: The Czech Government, through the SÚJB, established the Atomic Act No. 263/2016 Coll. which covers threat categorization, a national (radiation) emergency plan and recovery actions. Paragraph 153 of the Act provides for threat categorization in the area of radiation extraordinary event (REE). Paragraph 2 of the Decree No. 359/2016 Coll. on details of ensuring radiation extraordinary event management, provides a classification into five threat categories (A - E), in line with IAEA Safety Standard on Preparedness and Response for a Nuclear or Radiological Emergency GSR Part 7 Req. 4.19, which supersedes GS-R-2 (with the same title).

Recovery actions are established in Paragraph 158 of the Atomic Act as remedial action after a radiation accident. The IRRS team was informed that "remedial actions" is the term widely used in the Czech Republic and has the same meaning as 'recovery actions'. Further, Paragraph 22 of the Decree No. 359/2016 Coll. provides for the scope and way of the remedial actions.

The National Radiation Emergency Plan (NREP) is defined in the Atomic Act, Paragraph 4 (I) as a plan drawn up for the territory of the Czech Republic outside nuclear installation grounds or category IV workplaces to prepare for the management and implementation of a response to a radiation incident or radiation accident with an impact outside the emergency planning zone. The NREP which will be drawn up based on support materials for its drawing up forwarded by other ministries and other administration authorities to the SÚJB and Ministry of Interior (as given in Paragraphs 209, 211 and 213) approves the Government as is said in paragraph 210 of the Atomic Act. Annex 8 to the Decree No. 359/2016 Coll. provides detailed requirements for the content of the NREP. The Atomic Act in Paragraph 234 (2) provides for the SÚJB, Ministry of Interior and the Government to draw up and approve the NREP by 2020. The IRRS team was informed that the Czech Republic has not yet developed the NREP, but that plans are underway to develop the NREP in line with GSR Part 7. This plan will cover all relevant emergency response plans related to nuclear and radiological.

Status of the finding in the initial mission

Recommendation 14 (R14) is closed on the basis of progress made and confidence in effective completion as the legislation effectively covers the threat categories and recovery actions in line with GSR Part 7. The Atomic Act contains provisions for establishing a National Radiation Emergency Plan (NREP), still to be developed.

	2013 MISSION RECOMMENDATIONS, SUGGESTIONS
R15	Recommendation: SÚJB should establish requirements for emergency action levels in the Czech regulatory framework.
S16	Suggestion: SÚJB should consider having an inspector present on site in the Emergency Control Centre in emergency situations, in order to provide independent oversight and to communicate with the SÚJB Crisis Staff.
S17	Suggestion: SÚJB should consider improving its arrangements to provide information to the public and to the media during a radiation emergency, by establishing a comprehensive strategy in this regard.

Changes since the initial IRRS mission

Recommendation 15: The Atomic Act Paragraph 155 (3) provides requirements for ensuring preparedness and response to a radiation extraordinary event (REE). Details of emergency action levels (EAL) are provided in Paragraph 6 of the Decree No. 359, in line with GSR Part 7.

Suggestion 16: The SÚJB has established procedures (A-VDS 087(1)), concerning SÚJB site inspector to be present during emergency situations at the Technical Support Center, located at the licensee's Emergency Control Center at the site. The site inspector provides information to the SÚJB crisis staff. In the case of REE, the Head of SÚJB crisis staff is a member of the Central Crisis Staff, which coordinates all national response activities in the Czech Republic.

The SÚJB has also made arrangements to have the site inspector at the Emergency Control Center when conducting NPP emergency exercises. However, this is only the case during working hours. The IRRS team observed an exercise involving SÚJB and Dukovany NPP. It was noted that the exercise was well organized. The IRRS team was informed that SÚJB conducts such exercises every 2 years, alternating between the Temelin and Dukovany NPPs.

Suggestion 17: SÚJB has established VDK 090, which is a strategy for providing information to the public and media during a radiological emergency. The strategy aims at managing information flow from the SÚJB to the public and to the media. This information is provided through different forums such as traditional (e.g. press, radio, tv) and modern media (website and Facebook).

The established strategy (VDK 090), also stipulates provision for information to the public and media in normal situations. This may improve public understanding, confidence and cooperation during actual emergencies, since pre-informed public is more resistant to false information.

Status of the finding in the initial mission

Recommendation 15 (R15) is closed as the Czech Government has established requirements for emergency action levels in the national legislation.

Suggestion 16 (S16) is closed as SÚJB has made arrangements to have a site inspector present on site at the Emergency Control Center during emergency situations at nuclear power plants through establishment of VDS 087.

Suggestion 17 (S17) is closed as SÚJB has established a communication strategy (VDK 090), inter alia for communication with the media and the public during emergency situations.

$10.3.\ REQUIREMENTS\ FOR\ INFRASTRUCTURE$

There were no findings in this area in the initial IRRS mission.

11. ADDITIONAL AREAS IN THE FOLLOW-UP MISSION

11.1. CONTROL OF MEDICAL EXPOSURES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

S18

Suggestion: The Government should consider reviewing its national strategy regarding the official recognition of referral guidelines in order to facilitate their systematic review, update and dissemination.

Changes since the initial IRRS mission

Suggestion 18: By order of the Minister of Health (No. 23/2015, published on 23 October 2015), the *Working Group for Medical Exposures* (WG ME) was created and its status, working rules and composition was decided. This working group consists of representatives from the Ministry of Health, SÚJB and experts from professional bodies, and meets 4 times a year. In general terms, its objective is to analyse, prioritize and solve all issues related to medical exposures to ionizing radiation which are under the competence of Ministry of Health. One of the issues the WG ME identified having a high priority was the update of the referral guidelines and National Radiological Standards. To achieve this goal, the WG ME charged the Czech Radiological Society (the Society) to prepare an update of the referral guidelines for procedures in radiology. The IRRS team was informed that currently the Society has reviewed the referral criteria for the majority of the classical radiology procedures and it is starting the activities on CT (computed tomography) procedures. During the IRRS follow-up mission, the current draft version of the new Referral Guidelines was available in Czech language. It was anticipated that the draft document for all radiology procedures would be ready by the end of 2017.

The process for approval and dissemination of the reviewed referral guidelines was detailed as well: the draft will be reviewed by the WG ME, updated accordingly by the Society and then opened for stakeholder consultation. After a new update based on the results of this stakeholder consultation, the final draft will be submitted to the Minister of Health for approval and publication in the Journal of the Ministry of Health as part of the National Radiological Standards for general radiography. The IRRS team was informed that it is anticipated that this whole process would be ready by the end of 2018 for the radiology procedures.

No actions have been taken yet for updating the referral guidelines with respect to nuclear medicine procedures. It is, however, expected that the WG ME would charge the Czech Society for Nuclear Medicine with establishing a draft of these referral criteria immediately after the guidelines for radiology procedures would be finalised. The IRRS team was informed that the complete process for both radiology and nuclear medicine procedures would be finalised by 2020.

Status of the finding in the initial mission

Suggestion 18 (S18) is closed on the basis of the progress made and confidence in the effective completion of the review of the referral guidelines in the field of medical exposure as initiated by the Working Group for Medical Exposures under the Ministry of Health.

11.2. OCCUPATIONAL RADIATION PROTECTION

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

R16

Recommendation: The Government should ensure that the conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure and that there can be no substitute for measures for protection and safety.

Changes since the initial IRRS mission

Recommendation 16: The IRRS team was handed a copy of a letter detailing the position of the Ministry of Labour and Social Affairs related to the compensation scheme existing in the Czech Republic. These arguments forwarded are:

- the additional leave granted to category A radiation workers is not to be considered a protective measure in itself;
- the additional benefits do not form a replacement for correct protection against the hazards at the working place. They are rather required to compensate for the arduous working circumstances resulting from the additional requirements put onto the workers in these circumstances:
- these additional benefits are not only granted to workers exposed to ionising radiation (category A workers), but also to those working in "a deteriorated working environment under the influence of other aggravating factors, as listed in paragraph 6 section 2 of the Order of the Government".

The IRRS team considers that the Czech Republic has not taken necessary actions to align its Labour Law with the related requirement of GSR Part 3. Specifically, the compensation scheme contradicts para. 3.111 of GSR Part 3 stipulating: "The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure...". Occupational exposure to ionising radiation is not per se to be understood as arduous working circumstances.

Status of the finding in the initial mission

Recommendation 16 (R16) is open as the additional benefits scheme is still in place applicable to occupational exposure to ionising radiation (Category A workers in controlled areas).

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

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

R17

Recommendation: SÚJB should add the requirements related to remediation activity to the national legislation taking into account relevant statements established in WS-R-3 "Remediation of Areas Contaminated by Past Activities and Accident".

2013 MISSION RECOMMENDATIONS, SUGGESTIONS

Recommendation: The regulatory body should revise the current legal and regulatory framework to bring it in line with the requirements of GSR Part 3, including the following issues:

- a) complete the process for the determination of national DRLs for the remaining diagnostic procedures (interventional radiology, interventional cardiology, paediatric CT);
- b) require registrants and licensees that signs in appropriate languages are placed to request female patients undergoing a radiological procedure to notify, in case of pregnancy or breast feeding (for nuclear medicine);
- c) revise the equivalent dose limit for the lens of the eye;
- d) specify that the equivalent dose limit to the skin is to be applied to the most highly irradiated area of the skin;

R18

- e) review the precise formulation for the dose limits applicable to apprentices and students younger than 18 years of age;
- f) implement the concepts of existing and planned exposure situations and require that doses of workers during remedial actions in existing exposure situations are controlled by the requirements for occupational exposures in planned exposure situations;
- g) implement the concept of safety culture and require that the necessary conditions to promote a safety culture are provided.
- h) require explicitly that registrants and licensees shall provide, as appropriate, suitable storage for personal clothing at entrances to controlled areas where there is a risk for radioactive contamination;
- i) update the exemption levels for bulk amount of materials and clearance levels:
- j) update the existing regulations on consumer products.

Changes since the initial IRRS mission

Recommendation 17: The IRRS team was informed that during the revision process of the Atomic Act several statements regulating and managing existing exposure situations were incorporated into the new version of this Act based on the relevant requirements from the GSR Part 3 (paragraphs 102 and 103). Also, the IRRS team was provided a description of the approach to be implemented by SÚJB in case sites requiring remedial actions will be found. This approach is based on the requirements of the Paragraphs 102 (1) and (2) of the Atomic Act. According to these requirements, SÚJB has authority to develop and issue so called "General measures" – one of the types of administrative acts in the Czech Republic that has obligatory character and includes set of organizational arrangements to be required, planned and implemented by the local authority or responsible organization depending on the characteristics of the situation. However, the IRRS team noted that there are no regulations or guidelines detailing nor implementing these general provisions. In relation to this, the suggestion SF1 is made.

The IRRS team was provided with detailed explanations on how the activities performed by the operator of the facilities for uranium mining and milling in the Czech Republic – DIAMO – are regulated. SÚJB has issued a number of licenses to DIAMO authorising the operation of the facilities for uranium mining and milling (so called "category III workplace"), to discharge the radioactive substances to the environmental, to provide decommissioning of facilities that have stopped operations, including the monitoring of environment. It was concluded that the activities performed under DIAMO's responsibility are actually regulated by SÚJB as planned exposure situation according to the requirements for radiation protection established for occupational exposure.

Recommendation 18: The Government of the Czech Republic and SÚJB have effectively revised the legal and regulatory framework through the publication of the Atomic Act and the publication of the Decree No. 422/2016 Coll. on Radiation Protection and Security of a Radioactive Source (the Decree). This update was i.a. done with the aim to bring the Czech legislative and regulatory framework in line with the requirements from GSR Part 3.

More precisely, the following elements were observed:

- a) Paragraphs 84 and 85 of the Atomic Act contain the obligation to record the necessary parameters allowing estimation of medical exposure doses, to use of local DRLs in the optimisation of medical exposure and foresees setting of national DRLs, in principle to be considered as upper boundaries for the local DRL values, through implementing legislation. The Annex 22 to the Decree reviews and updates the previously existing national DRLs. These updated values cover most of the radiology and nuclear medicine procedures. Additionally, the Annex contains the national DRL values for interventional cardiology procedures which were not published at the moment of the initial IRRS mission. Currently SÚRO (SÚJB's TSO) is conducting a research project to collect and treat the necessary data in order to set national DRL's for paediatric CT procedures. Simultaneously, SÚJB is collecting the data required for setting the DRL values for interventional radiology procedures. The IRRS team was informed on the strategy and methodology that are being followed in both cases (selection of hospital centres, treatment of the data, using the 75-percentile as DRL, ...);
- b) workplaces intended for x-ray diagnostics and radiotherapy and workplaces intended for the therapeutic or diagnostic application of a radionuclide shall post, in a visible place, a notification of the necessity to inform healthcare provider employees of pregnancy prior to the execution of medical exposure, as required by Paragraphs 75 (2) and 78 (6) of the Decree. An example of such notification to the patients is published in Czech language on the website of SÚJB and was sent to the health care centres in the country. Additionally, a special topic is dedicated on pregnancy and ionising radiation on SÚJB's Web Conference.
- c) Paragraph 4 (1) (b) of the Decree limits the equivalent dose to the lens of the eye for occupationally exposed workers to 100mSv over 5 consecutive years and simultaneously to 50mSv over one calendar year. At the same time, Paragraph 5 (3) (b) limits the equivalent dose to the lens of the eye of pupils and students between the ages of 16 and 18 who have to work with a source of ionising radiation during their studies to 15mSv over a calendar year. Additionally, Paragraph 5 (3) (b) limits the equivalent dose to the lens of the eye of members of the general public (including pupils under 16 year of age, according to Paragraph 5 (4)) to 15mSv per calendar year.

From a practical point of view, the follow-up on the respect of this revised dose limit will be based on an estimation of the dose to the lens of the eye based on the registered chest dose (above the lead apron if an apron is worn). The ICRP methodology will be used for

this estimation. If this estimation of the eye lens dose reaches 15mSv, the radiation protection officer of the facility will be requested to perform a more precise estimate of the actual eye lens dose, taking into account the actual exposure circumstances (e.g. use of glasses, ...). If the resulting value remains high, the use of an eye lens dosimeter will be required. More in general, in all cases where the dose at the chest (above the lead apron if applicable) is larger than 50mSv, an eye lens dosimeter will be required.

- d) Paragraphs 3 (c), 4 (1) (c) and 5 (3) (c) of the Decree state that the equivalent dose limit to the skin is to be applied to every square centimetre of the skin, regardless of the exposed surface;
- e) The formulation of Paragraph 5 of the Decree for the dose limits applicable to apprentices and students younger than 18 years of age have been revised and stipulate clearly that any exposure to apprentices and students younger than 16 years of age shall be limited to the dose limits for the general public;
- f) The concepts of planned and existing exposure situations are implemented in the Atomic Act (Paragraphs 2 (2) (e) and further; specifically related to existing exposure situations: Paragraphs 96-103). In a very general manner, Paragraph 102 (3) of the Atomic Act requires that the exposure of the workers during remedial actions has to be controlled by the requirements for occupational exposure under planned exposure situations. However, the IRRS team noted that no regulations are detailing nor implementing these general provisions. In relation to this, the suggestion SF1 is made;
- g) The Atomic Act introduces the concept of safety culture through a requirement on the management system of the registrants and licensees (Paragraph 30 (7)). The provision requires that the management system shall be introduced in a manner ensuring that through this system characteristics and attitudes of persons (hereinafter "safety culture") performing activities related to the use of nuclear energy and activities in exposure situations and of their personnel ensuring nuclear safety, radiation protection, technical safety, radiation monitoring, accident & incident management and security are permanently developed and regularly evaluated and are approached with a seriousness corresponding to their importance. Additionally, Paragraph 50 of the Decree requires registrants and licensees to inform exposed workers and trainees for work in controlled and supervised areas of the importance of a safety culture for ensuring radiation protection;
- h) The requirement for registrants and licensees to provide, as appropriate, suitable storage for personal clothing at entrances to controlled areas where there is a risk for radioactive contamination is not necessary to be present in the revised legislative and regulatory framework (Atomic Act and Decree 422/2016), because requirement related to dressing rooms and storage of personal clothing at the entrances to certain hazardous working areas is present in the Governmental Decree No. 361/2007 Coll. (Paragraph 54(3)) issued by the Ministry of Health. Furthermore, the necessary requirements are present concerning the use of protective wear and contamination measurement upon leaving controlled areas presenting a risk for contamination. The IRRS team was furthermore informed that the need for suitable storage for personal clothing will be included in a SÚJB guide of good practice (to be published) and that SÚJB is systematically requiring the presence of suitable storage for personal clothing when reviewing the license application files, based on Paragraph 24(3) of the Atomic Act. In this respect, the IRRS team draws the attention of SÚJB to the need to have the requirement explicitly mentioned in the internal guides and procedures in order to guarantee this systematic verification by the SÚJB experts;

- i) Based on the requirements of GSR Part 3 and the tables I.1 and I.2 annexed to GSR Part 3, the exemption levels for both bulk amounts and moderate amounts of materials and the clearance levels for solid materials in the Czech Republic have been updated through the annex 7 to the Decree. The actual clearance of solid materials is governed by Paragraphs 104 and 105 of the Decree and include a summation rule in case of mixtures of radionuclides. In addition to the clearance levels based on activity concentration values as foreseen in GSR Part 3, the Decree also contains clearance levels for surface contaminated objects. The clearance levels defined in this case correspond to the exclusion values from the transport regulations (SSR-6);
- i) The Atomic Act clearly defines the concept of consumer products containing radionuclides (Paragraph 2(2)(h)) as any product which may be sold or made available to the public without special regulation or control after sale and either into which the radionuclides have been incorporated or produced deliberately or which is generating ionising radiation. The Act requires in its Paragraph 9(2)(g) a specific license to be granted by SÚJB for the deliberate addition of a radioactive substance to a consumer product or importing such products, even when the activity levels would be below exemption levels (Paragraph 67(3) of the Atomic Act). The required documentation when applying for such a license is clearly detailed in the annex 1-2.g to the Atomic Act. Additionally, the Paragraph 137(2)(d) of the Atomic Act requires type-approval by SÚJB for consumer goods containing radionuclides. The minimal content of the documentation intended for the end-user of any consumer product containing radionuclides is described in Paragraph 68(1)(i) of the Atomic Act. Finally, the Paragraph 203 empowers SÚJB inspectors to perform inspection and to take enforcement actions with respect to addition of radioactive substances to consumer products in case the requirements of the Act are not respected. The IRRS team draws the attention of SÚJB to the importance of systematically using the correct terminology and defined terms in legislative and regulatory documents.

The IRRS team was informed that an operational process to deal with requests on consumer products containing radionuclides exists within SÚJB and that several licenses and type approvals in this matter have already been delivered. Following cases were quoted: ³H containing watches, ³H containing optical sights of guns, outdoor lighting containing ³H, zooming devices for reading maps containing ³H, lightbulbs containing ⁸⁵Kr or ²³²Th.

Status of the finding in the initial mission

Recommendation 17 (R17) is closed on the basis of the progress made and confidence in the effective completion in further implementation of the requirements mentioned in the Atomic Act related to remediation activities in existing exposure situations, as the actual processes implementing the legislative framework applicable to these situations have not been developed nor tested yet (see SF1).

Recommendation 18a (R18a) is closed on the basis of the progress made and confidence in the effective completion as the existing national DRL values have been revised, the national DRL's for interventional cardiology have been established and a clear strategy and methodology for establishing the national DRL's for the remaining procedures have been established. The DRL's for interventional radiology and paediatric CT have however still to be determined.

Recommendation 18b (R18b) is closed as the Decree 422 require registrants and licensees to post signs in appropriate language requesting female patients undergoing a radiological procedure to notify in case of pregnancy or breast feeding (for nuclear medicine).

Recommendation 18c (R18c) is closed as the Decree 422 revises the equivalent dose limit to the lens of the eye in line with the requirements of GSR Part 3.

Recommendation 18d (R18d) is closed as the Decree 422 revises the formulation for the equivalent dose limit to the skin, to bring it in line with the requirements of GSR Part 3.

Recommendation 18e (R18e) is closed as the Decree 422 revises the formulation for the dose limits applicable to apprentices and students younger than 18 years of age, to bring them in line with the requirements of GSR Part 3.

Recommendation 18f (R18f) is closed on the basis of the progress made and confidence as the Atomic Act implements the concepts of planned exposure situation and existing exposure situation and requires in a very general way that during remedial activities the dose to the workers has to be controlled by the requirements for planned exposure situations. Further implementation of the requirements related to remediation activities in existing exposure situations mentioned in the Atomic Act is however necessary in order to clarify the very general provisions in the Act in this field (see SF1).

Recommendation 18g (R18g) is closed as the Atomic Act and the Decree 422 introduce the concept of safety culture and make the necessary provisions to underline its importance for ensuring effective radiation protection.

Recommendation 18h (R18h) is closed on the basis of the progress made and confidence that arrangements related to the need to provide suitable storage for personal clothing at entrances to controlled areas where there is a risk for radioactive contamination will be taken into account during the licensing process.

Recommendation 18i (R18i) is closed as the Annex 7 to the Decree 422 contains the relevant exemption and clearance values, in line with the corresponding tables from GSR Part 3.

Recommendation 18j (R18j) is closed as the Atomic Act provides for the intentional addition of radioactive material to consumer products in line with the requirements of GSR Part 3.

New observations from the follow-up mission

(1)

The IRRS team noted the relative general formulations in the Atomic Act related to existing exposure situations and the related remediation activities. The IRRS team was also informed that SÚJB considers that unknown contaminated areas can appear only very unlikely on the territory of the Czech Republic, there are no regulations in this field explicitly describing individual steps and requirement for the management of such situations because final solution will be finally depending on the particular circumstances.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Only general provisions exist in the Atomic Act related to existing exposure situations and the related remediation activities, while neither regulations nor guidelines in this field exist.

BASIS: GSR Part 3 Req. 5.4 states that "The regulatory body or other relevant authority assigned to establish a protection strategy for an existing exposure situation shall ensure that it specifies:

- (a) The objectives to be achieved by means of the protection strategy;
- (b) Appropriate reference levels."

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FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES				
	BASIS: GSR Part 3 Req. 5.5 states that "The regulatory body or other relevant authority shall implement the protection strategy, including:			
(2)	(a) Arranging for evaluation of the available remedial actions and protective actions for achieving the objectives, and for evaluation of the efficiency of the actions planned and implemented;			
	(b) Ensuring that information is available to individuals subject to exposure on potential health risks and on the means available for reducing their exposures and the associated risks."			
SF1	Suggestion: SÚJB should consider developing regulations and guidelines to detail and complement the general provisions in the Atomic Act on existing exposure situations and remedial activities.			

During the discussions, the IRRS team was informed that SÚJB is running a Web Conference. This is a special section of the SÚJB public website in which the general public can ask any question related to the matters for which SÚJB has competences. SÚJB engages itself to provide answers to the questions within one week. Questions and answers are published on the public website after a verification of the content and the appropriateness of the technical language used.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES				
Observation: SÚJB is actively engaged in communication with the public through a Web Conference, on which publically answers are supplied to any relevant question from the public in a timely manner and in a language adapted to laymen.				
(1)	BASIS: GSR Part 3 Req. 2.36 states that "The regulatory body shall establish mechanisms for communication and discussion that involve professional and constructive interactions with relevant parties for all protection and safety related issues."			
GPF1	Good Practice: SÚJB is actively engaged in communication with the public using a Web Conference.			

IRRS FOLLOW-UP MISSION TEAM



APPENDIX I - LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:					
TIIPPANA Petteri	Radiation and Nuclear Safety Authority (STUK) petteri.tiippana@str				
CIUREA Cantemir	National Commission for Nuclear Activities Control (CNCAN) <u>cantemir.ciurea@cncan.ro</u>				
KABORO Beth	Radiation Protection Board	kaborobeth@gmail.com			
ROOS Gerhard	Nuclear Safety Standards Commission (KTA)	gerhard.roos@bfe.bund.de			
SONCK Michel	Federal Agency for Nuclear Control (FANC)	michel.sonck@fanc.fgov.be			
UHRIK Peter	Nuclear Regulatory Authority (UJD)	peter.uhrik@ujd.gov.sk			
	IAEA STAFF MEMBERS				
NICIC Adriana	Division of Nuclear Installation Safety	t.kobetz@iaea.org			
KILOCHYTSKA Tetiana	Division of Nuclear Safety and Radiation Waste	t.kilochytska@iaea.org			
SHADAD Ibrahim	HADAD Ibrahim Division of Nuclear Safety and Radiation Waste				
DANI Mario	Division of Nuclear Installation Safety	m.dani@iaea.org			
LIAISON OFFICER					
KRS Petr	State Office for Nuclear Safety (SÚJB)	petr.krs@sujb.cz			

APPENDIX II - MISSION PROGRAMME

Time	Mon 15 May	Tue 16 May	Wed 17 May	Thu 18 May	Fri 19 May	Sat 20 May	Sun 21 May	Mon 22 May	Tue 23 May							
9:00-10:00																
10:00-11:00	Team Arrival	Entrance Meeting	Interviews	Interviews	Discussion of findings/ report by the team	Individual reading of the report	Host reads report TL prepares presentation	Review of host's comments	Exit Meeting							
11:00-12:00						Discussion of results of cross-reading										
13:00-14:00				TM finalize	Discussion of findings with	Collective reading of the		Discussion with the Host								
14:00-15:00		Interviews Initial Team Meeting	Interviews	findings/ TM write report	findings/	counterpart	report Finalise draft Report	Social Event	Preparation of the press release							
15:00-16:00	Team		interviews	interviews	interviews								Review of the Executive Summary			n Members
16:00-17:00	- inteeting		Written preliminary findings delivered	Final findings with text delivered	Team revises report based on discussions	Submission of Report to IRRS Admin		Final Draft to the Host	Departures of Team Members							
17:00-18:00		Daily Team Meeting	Daily Team Meeting	Daily Team Meeting	Daily Team Meeting	Submission of the Draft Report to the	Written comments presented by the Host		Dek							
20:00-24:00		TM write findings	Secretariat edits findings TM write report	Secretariat edits report TM Read Draft	Cross reading TL drafts Executive Summary	- Host		Farewell Dinner								

APPENDIX III - MISSION COUNTERPARTS

	IRRS Experts	SÚJB Lead Counterpart	SÚJB Support Staff			
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT					
	Mr. Petteri TIPPANA Ms. Tetiana KILOCHYTSKA Mr. Cantemir CIUREA Mr. Gerhard ROOS	Mr. Petr Krs	Ms. Miroslava Leflerová, Mr. Štěpán Kochánek, Mr. Jan Kropáček, Mr. Radim Doležal, Mr. Marek Bozenhard, Mr. Peter Lietava			
2.	GLOBAL NUCLEAR SAI	FETY REGIME				
	Mr. Petteri TIPPANA Ms. Tetiana KILOCHYTSKA	Mr. Petr Krs	Ms. Miroslava Leflerová, Mr. Štěpán Kochánek			
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY					
	Mr. Cantemir CIUREA Mr. Gerhard ROOS	Mr. Petr Krs	Ms. Miroslava Leflerová, Mr. Štěpán Kochánek			
4.	MANAGEMENT SYSTE	M OF THE REGULATORY BODY				
	Ms. Adriana NICIC	Mr. Petr Krs	Ms. Miroslava Leflerová			
5.	AUTHORIZATION					
	Mr. Cantemir CIUREA Mr. Peter UHRÍK	Mr. Zdeněk Tipek	Ms. Michaela Ratajová, Mr. Tomáš Kadeřábek			

	IRRS Experts	SÚJB Lead Counterpart	SÚJB Support Staff			
6.	REVIEW AND ASSESSMENT					
	Mr. Cantemir CIUREA Mr. Peter UHRÍK	Mr. Zdeněk Tipek	Ms. Michaela Ratajová, Mr. Tomáš Kadeřábek			
7.	INSPECTION					
	Mr. Peter UHRÍK	Mr. Zdeněk Tipek	Mr. Zdeněk Witkovský, Mr. Peter Lietava, Mr. Štěpán Kochánek			
8.	ENFORCEMENT					
	Mr. Peter UHRÍK	Mr. Zdeněk Tipek	Mr. Zdeněk Witkovský, Mr. Peter Lietava, Mr. Štěpán Kochánek			
9.	REGULATIONS AND GUIDES					
	Mr. Gerhard ROOS	Mr. Petr Krs	Mr. Zdeněk Tipek, Ms. Miroslava Leflerová, Mr. Peter Lietava			
10.	EMERGENCY PREPARI	EDNESS AND RESPONSE				
	Ms. Beth KABORO	Ms. Helena Chudá Ms. Věra Starostová				
11.	ADDITIONAL AREAS					
	Mr. Michel SONCK	Mr. Karla Petrová	Ms. Ivanka Zachariášová, Ms. Hana Podškubková, Mr. Milan Hort, Mr. Miroslav Jurda			

APPENDIX IV - RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE PREVIOUS IRRS MISSION THAT REMAIN OPEN

Section	Module	R/S	Recommendation/Suggestion	
4.5	4	R5	Recommendation 5 (R5) is open as SÚJB has not fully completed the development and implementation of its Integrated Management System. This project is planned to be completed by 2020.	
6.2	6	S11	Suggestion 11 (S11) is open as SÚJB has not yet developed adequate resources to regularly, independently and comprehensively assess probabilistic safety analyses for nuclear power plants.	
11.2	11	R16	Recommendation 16 (R16) is open as the additional benefits scheme is still in place applicable to occupational exposure to ionising radiation (Category A workers in controlled areas).	

APPENDIX V - RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2017 IRRS FOLLOW UP MISSION

Section	Module	RF/SF/GPF	Recommendation, Suggestion or Good Practice
11.3	11	SF1	SÚJB should consider developing regulations and guidelines to detail and complement the general provisions in the Atomic Act on existing exposure situations and remedial activities.
11.3	11	GPF1	SÚJB is actively engaged in communication with the public using a Web Conference.

APPENDIX VI - REFERENCE MATERIAL PROVIDED BY SÚJB

Implementation of the CPPNM Principles into the Czech Legal Framework; Implementation of GSR Part 1 into the Czech Legal framework Implementation of the GSR Part 2 – Leadership Man Management for Safety into the Czech Legal Framework Implementation of the GSR Part 3 into the Czech Legal Framework Implementation of the GSR Part 4 into the Czech legal Framework Requirements of IAEA Document GRS 5 Predisposal management of Radioactive Waste and Its Implementation into the Czech Legal Framework Implementation of the GSR Part 6 into the Czech Legal Framework Implementation of the GSR Part 7 into the Czech Legal framework Implementation of the Site Evaluation for Nuclear Installations, NR-R-3 (Rev. 1) into the Czech Legal Framework Implementation of the Safety Fundamentals into the Czech Legal Framework Responses to the Recommendations and Suggestions of the IRRS 2013 Mission Order of the Management & Technical Support Section Director No. 1/2017 to Prevent Any Conflict of Interests in Providing the Specialized Technical Support SÚJB Integrated Management System Manual Module 1: Responsibilities and Function of the Government – Suggestion 2 Module 2: Global Nuclear Safety Regime Module 8: Enforcement – Recommendations 8 and 9 Module 9: Regulations and Guides – Recommendation 10 **Enforcement Policy** VDK 090 – Strategy for informing the Public and Media in a Radiological Emergency VDK 097 – The Long-Term Strategy for Development of Human Resources VDK 100 – SÚJB Integrated Management System Manual VDK 101 – Strategy of the SÚJB VDS 087 – Rules Concerning the Inspectors of Site Inspector Division at Technical

Support Centre

VDS 104 - Ratings within the Authorized Lofe Cycle of nuclear Facilities within the Scope of the Nuclear Safety Section (Hodnocení v rámci autorizovaných fází životnosti jaderných zařízení v působnosti sekce jaderné bezpečnosti in Czech)

VDS 106 - Rules for Assessing Professional Recommendations (in Czech)

VDI 096 – Evaluation of Limits and Conditions, Programme of Operational Inspections and their Changes in NS Section (Hodnocení Limitů a podmínek, Programu provozních kontrol a jejich změn v sekci JB in Czech)

VDI 102 – Evaluation of the System for the preparation of Selected Staff and a List of NS Relevant Activities and a Description of the System of Education, Training and Training of Staff Including a Description of the Qualifications of Employees (Hodnocení Popisu systému přípravy vybraných pracovníků a Seznamu činností důležitých z hlediska JB a popisu systému vzdělávání, odborné přípravy a výcviku pracovníků včetně popisu kvalifikace pracovníků – in Czech)

Decision (Rozhodnutí – see in the attachment)

Building Permit (Stavební povolení – see in the attachment)

Decree No. 162/2017 Coll about Safety Assessment (in Czech)

Decree No. 21/2017 on Ensuring of Nuclear Safety

APPENDIX VII - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- 1. IAEA SAFETY STANDARDS SERIES No. SF-1 Fundamental Safety Principles
- 2. IAEA SAFETY STANDARDS SERIES No. GSR PART 1 Governmental, Legal and Regulatory Framework for Safety
- 3. IAEA SAFETY STANDARDS SERIES No. GSR PART 3 Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
- 4. IAEA SAFETY STANDARDS SERIES No. GSR PART 7 Preparedness and Response for a Nuclear or Radiological Emergency
- 5. **IAEA SAFETY STANDARDS SERIES No. GS-R-3** The Management System for Facilities and Activities
- 6. IAEA SAFETY STANDARDS SERIES No. NS-R-1 Safety of Nuclear Power Plants: Design
- 7. IAEA SAFETY STANDARDS SERIES No. NS-R-2 Safety of Nuclear Power Plants: Operation
- 8. IAEA SAFETY STANDARDS SERIES No. NS-R-4 Safety of Research Reactors
- 9. IAEA SAFETY STANDARDS SERIES No. GS-G-1.1- Organization and Staffing of the Regulatory Body for Nuclear Facilities
- 10. IAEA SAFETY STANDARDS SERIES No. GS-G-1.2 Review and Assessment of Nuclear Facilities by the Regulatory Body
- **IAEA SAFETY STANDARDS SERIES No. GS-G-1.3-** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
- 12. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.4** Documentation for Use in Regulatory Nuclear Facilities
- **IAEA SAFETY STANDARDS SERIES No. GS-G-2.1** Arrangements for Preparedness for a Nuclear or Radiological Emergency
- 14. IAEA SAFETY STANDARDS SERIES No.GS-G-3.1 Application of the Management System for Facilities and Activities
- 15. IAEA SAFETY STANDARDS SERIES No. GS-G-3.2 The Management System for Technical Services in Radiation Safety
- **IAEA SAFETY STANDARDS SERIES No. RS-G-1.3 -** Assessment of Occupational Exposure Due to External Sources of Radiation
- 17. IAEA SAFETY STANDARDS SERIES No. RS-G-1.4 Building Competence in Radiation Protection and the Safe Use of Radiation Sources
- **18. IAEA SAFETY STANDARDS SERIES No. NS-G-2.10 -** Periodic Safety Review of Nuclear Power Plants Safety Guide
- 19. **IAEA SAFETY STANDARDS SERIES No. NS-G-211** A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide
- 20. INTERNATIONAL ATOMIC ENERGY AGENCY Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

APPENDIX VIII - SÚJB ORGANIZATIONAL CHART

