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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

THE REPUBLIC OF CROATIA

Zagreb, Croatia

7 – 17 June 2015

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

dzrns
DRŽAVNI ZAVOD ZA RADIOLOŠKU I NUKLEARNU SIGURNOST
STATE OFFICE FOR RADIOLOGICAL AND NUCLEAR SAFETY

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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
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THE REPUBLIC OF CROATIA

Integrated Regulatory Review Service

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THE REPUBLIC OF CROATIA

Mission dates:	*7 to 17 June 2015*
Regulatory body visited:	*State Office for Radiological and Nuclear Safety*
Location:	*Zagreb, Croatia*
Regulated facilities and activities in the mission scope:	*Radiation sources in industrial and medical facilities, research facilities, emergency preparedness and response, medical exposure, occupational exposure*
Organized by:	*International Atomic Energy Agency*

IRRS REVIEW TEAM	
MAKAROVSKA Olga	Team Leader (Ukraine)
BOSNJAK Jovica	Reviewer (Bosnia and Herzegovina)
DUSIC Darja Slokan	Reviewer (Slovenia)
LANRIVAIN Isabelle	Reviewer (France)
ŠKRABAN Aleš	Reviewer (Slovenia)
STATKUS Vaidas	Reviewer (Lithuania)
MADDEN Jack	Reviewer (Ireland)
NIZAMSKA Marina	Reviewer (Bulgaria)
PAŠKOVÁ Zuzana	Reviewer (Czech Rep)
ZINGER Irene	Reviewer (Australia)
DJERMOUNI Belkacem	IAEA Team Coordinator
NESTOROSKA MADJUNAROVA Svetlana	IAEA Reviewer Area Facilitator
PACHECO Ronald	IAEA Reviewer Area Facilitator
SWOBODA Zumi	IAEA Administrative Assistant

IAEA-2015

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

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EXECUTIVE SUMMARY

At the request of the Government of the Croatia, an international team of senior safety experts met representatives of the State Office for Radiological and Nuclear Safety (SORNS) from 6 June to 17 June 2015 to conduct an Integrated Regulatory Review Service (IRRS) mission. During the mission there were meetings with representatives of other organizations having responsibilities for radiation protection and safety in Croatia. The purpose of the peer review was to review the Croatian regulatory framework for radiation safety and to exchange knowledge and experience on regulatory issues.

The review team compared the Croatian 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 IRRS team members and Croatian counterparts.

The IRRS team comprised ten senior regulatory experts from nine IAEA Member States, three IAEA technical officers and one IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, public and environmental exposure control, waste management and decommissioning.

In addition, policy issues of current high priority for Croatia were discussed specifically: Revision of emergency planning zones in the Republic of Croatia and Implementation of the Strategy for Management of Radioactive Waste, Disused Sources and Spent Fuel in the Republic of Croatia.

The IRRS review addressed the national framework for safety, regulatory infrastructure and the regulatory control of all facilities and activities that are regulated in Croatia.

The mission included observations of regulatory activities and interviews and discussions with regulatory staff, representatives from Ministry of Health, National Protection and Rescue Directorate to assess the effectiveness of the regulatory system and to validate the comprehensive, transparent and thoroughly considered self-assessment performed by SORNS.

Visits were made to 3 sites: the hospital KBC Sestre milosrdnice (University Hospital Center “Sisters of Charity”); Non-Destructive Testing (NDT) Company: Industrial facility: ZIT d.o.o. (ZIT ltd. – Office for Welding, Testing and Technology); TSO organization: IMI (Institute for Medical Research and Occupational Health (IMROH). The IRRS team members observed regulatory working practices during inspections carried out by SORNS inspectors, including discussions with licensee personnel and management.

SORNS provided the IRRS team with advance reference material and documentation including the results of the self-assessment in all areas within the scope of the mission. Throughout the mission, the IRRS team was extended full cooperation in regulatory, technical, and policy issues by all parties; in particular, the staff of SORNS, provided the fullest practicable assistance and demonstrated openness and transparency.

The IRRS team made the following general observations:

- Croatia established SORNS as an effectively independent regulatory body empowered by the Act for Nuclear and Radiation Safety to fulfil their regulatory responsibilities, roles and functions in line with the IAEA standards.
- Croatia is an active member of the international safety regime.

- Croatia established the National Strategy for Management of Radioactive Waste, Disused Sources and Spent Fuel and started its implementation.

The IRRS team identified areas for Croatian Government and SORNS, where significant efforts for improvement are needed to comply with International Standards in particular:

- Review and strengthen the governmental, legal and regulatory framework for safety in order to make it consistent with IAEA safety standards in particular establishing and implementing the graded approach in all regulatory processes.
- Providing SORNS with the necessary human and financial resources to discharge effectively its statutory obligations and responsibilities.
- Improvement of SORNS staff qualification and competence for effective performing of regulatory functions.
- Establishment of an integrated management system in line with the requirements of IAEA safety standards to achieve stability and consistency of the regulatory control. This system should include processes and procedures for authorization, review and assessment, inspection, enforcement, emergency preparedness and response.
- Improving patient protection in medical exposure situations in close cooperation with the Ministry of Health and professional societies.

The IRRS team identified a number of recommendations and suggestions where improvements in the area of radiation safety regulation are necessary or desirable.

Based on the recommendations and suggestions made by the IRRS mission SORNS should consider updating the Action Plan which has been submitted as part of its self-assessment. When finalized this Action Plan could be used as a basis for a national project to be supported by the IAEA Technical Cooperation Programme.

The IRRS review team findings are summarized in Appendix V.

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

I. INTRODUCTION

At the request of the Government of the Republic of Croatia, an international team of senior safety experts met representatives of the regulatory body of the host country State Office for Radiological and Nuclear Safety (SORNS) from 7 to 17 June 2015 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review, which was funded by the Technical Cooperation Programme (CRO9011 "Supporting an Integrated Regulatory Review Service Mission"), was to review Croatia's regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Republic of Croatia in 4 April 2013. A preparatory mission was conducted 3 – 4 November 2014 at SORNS Headquarters in Zagreb to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Croatia and their related safety aspects and to agree the scope of the IRRS mission. Where specific facilities and / or activities would not be included in the scope of the IRRS mission, Croatia undertook to provide explanation for the exclusion.

The IRRS review team consisted of 10 senior regulatory experts from 9 IAEA Member States, 3 IAEA staff members and 1 IAEA administrative assistant. The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, control of medical exposure, public and environmental exposure control, waste management and decommissioning.

In addition, policy issues were discussed, including: Revision of Emergency planning zones and Implementation of the Strategy for Management of Radioactive Waste, Disused Sources and Spent Fuel in the Republic of Croatia

SORNS conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of SORNS self-assessment and supporting documentation were provided to the IRRS review team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics within the agreed scope through review of Croatia's advance reference material, conduct of interviews with management and staff from SORNS and direct observation of SORNS's regulatory activities at regulated facilities. Meetings with the Ministry of Health and the National Protection and Rescue Directorate were also organized.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Croatia's radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Croatia. It is expected this IRRS mission will facilitate regulatory improvements in Croatia and other Member State, utilizing the knowledge gained and experiences shared between SORNS and IRRS reviewers and the evaluation of Croatia's regulatory framework for nuclear safety.

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

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

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

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

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

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

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

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

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

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

j) promoting the application of IAEA Safety Requirements; and

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of the Republic of Croatia, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 3 to 4 November 2014. The preparatory meeting was carried out by the appointed Team Leader Ms Olga Makarovska, and the IAEA representative, Mr Ahmad Al Khatibeh.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of SORNS represented by Director General Saša Medaković, and other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Radiation sources facilities and activities;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Control of radioactive discharge and materials for clearance;
- Selected policy issues.

SORNS Director General made presentations on the national context, the current status of SORNS and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Croatia in June 2015.

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

The SORNS Liaison Officer for the IRRS mission was confirmed as Ms Stela Popović.

SORNS provided IAEA with the advance reference material (ARM) for the review at the end of March 2015. In preparation for the mission, the IAEA review team members reviewed Croatia's advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 7 June, 2015 in Zagreb, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on Monday, 8 June, 2015, with the participation of SORNS senior management and staff. Opening remarks were made by Director General SORNS Mr Saša Medaković, and Dr Marijan Cesarik, Deputy Minister of Health, Ms Olga Makarovska, IRRS Team Leader. Ms Nevenka Novosel gave an overview of Croatia's context and SORNS activities. Mr Davor Rašeta gave a regulatory overview on the results of the Self-Assessment on the Regulatory Infrastructure for Safety (SARIS).

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Croatia and with recommendations and suggestions for improvement. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

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

The IRRS exit meeting was held on Tuesday, 16 June, 2015. The opening remarks at the exit meeting were presented by SORNS Director General Mr Saša Medaković and were followed by the presentation of the results of the mission by the IRRS Team Leader Ms Olga Makarovska. Closing remarks were made by Mr Pil-Soo Hahn, IAEA, Director, Division of Radiation, Transport and Waste Safety.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

In Croatia the Constitution stipulates the process by which the acts (first level of legislation) and regulations (second level legislation) can be issued. The parliament, as a representative body of the people, is vested with legislative power by adopting laws. The Government exercises executive powers by proposing bills to the Parliament, executes laws of the Parliament and adopts decrees (regulations) to implement laws. The Law on the State Administration in its Article 18 provides that the ministers, the heads of state offices and directors of governmental authorities (as for example the State Office for Radiological and Nuclear Safety - SORNS) adopts ordinances, orders and instructions for the implementation of laws and other regulations when explicitly authorized, within the limits of the authorization granted.

The main legislative instrument in the field of radiation (radiological) and nuclear safety in Croatia is the Act on Radiological and Nuclear Safety, published in Official Gazette No. 141/13 (hereinafter referred to as the 2013 Act), which was amended in April 2015.

The 2013 Act states that measures for radiological safety, measures for physical protection and measures for non-proliferation of nuclear weapons in performing nuclear operations and operations involving sources of ionizing radiation has been established to ensure adequate protection of individuals, society and the environment, in the present and in the future, against harmful effects of ionizing radiation, and to ensure safe performance of operations involving ionizing radiation sources, nuclear operations, radioactive waste management and physical protection of ionizing radiation sources and nuclear installations.

The graded approach commensurate with the radiation risk associated with the facilities and activities (performance of nuclear operations and of operations involving sources of ionizing radiation) is not explicitly mentioned in the 2013 Act and/or implemented in its regulations and ordinances contrary to main basic safety principles, such as justification, optimization and dose limitation. On the other hand, the requirements prescribed in regulations and ordinances are partially based on a graded approach.

However, the Croatian Government has not produced nor adopted a separate document describing its national policy and strategy for radiation and nuclear safety. Such document should take into account of the following:

(a) the fundamental safety objective and the fundamental safety principles;

(b) binding international legal instruments, such as conventions and other relevant international instruments;

(c) the specification of the scope of the governmental, legal and regulatory framework for safety;

(d) the need and provision for human and financial resources;

(e) the provision and framework for research and development;

(f) adequate mechanisms for taking account of social and economic developments; and

(g) the promotion of leadership and management for safety, including safety culture.

The objective of producing such a document is to demonstrate the Government’s long-term commitment to safety and to ensure the appropriate national infrastructure in this area and the appropriate focus and commitment to safety are maintained.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The Croatian Government has not established a comprehensive national policy outlining its commitment to safety and strategy for implementing a national policy with the objective to demonstrate the Government's long-term commitment to safety and provide a national co-ordinated plan to ensure the appropriate national infrastructure.
(1)	**BASIS: GSR Part 1 Requirement 1 states that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."*
R1	**Recommendation:** The Government should establish a national policy and strategy for safety in accordance with Requirement 1 of GSR Part 1.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

As mentioned earlier, the current radiation and nuclear safety legislation is based on the 2013 Act (as amended in 2015); the 2013 Act include provisions related to: approval for performance of operations involving ionizing radiation sources; license for use of ionizing radiation sources; approval for performance of nuclear operations; approval for the construction, trial operation and operation of nuclear installation; approval for performance of operations involving management of radioactive waste, disused sources and spent nuclear fuel. All licences and approvals are issued by the State Office for Radiological and Nuclear Safety (SORNS). In addition, import, export, transport and transit of ionizing radiation sources, special equipment, radioactive waste, spent nuclear fuel and disused sources may be carried out by legal and natural persons on the basis of an approval or a license issued by SORNS. Details on the authorization process, the content of application and submitted documentation, criteria and conditions are prescribed in the ordinances issued by the Director General of SORNS. Provisions on review and assessment are also part of those ordinances but are not stipulated in the 2013 Act.

The responsibilities of SORNS are stipulated in the 2013 Act. SORNS was established already in 2010 by the previous Act on Radiological and Nuclear Safety, and took over functions and tasks as well as civil servants, equipment, archives and other documentation, operating resources, financial means and rights and obligations of both the State Office for Radiation Protection and the State Office for Nuclear Safety. SORNS' authority and responsibilities are prescribed in detailed in the 2013 Act. SORNS is the sole administrative authority/regulatory body empowered to ensure that the fundamental safety objectives and safety principles of the 2013 Act on Radiological and Nuclear Safety are met.

No appeal may be filed to SORNS against its decision (granted or denied) but an administrative dispute may be initiated to the Court. Although the 2013 Act has no special and/or specific provisions on the involvement of the interesting parties in the decision-making process, provisions with respect to the licensing process are stipulated in the General Administrative Procedure Act. With respect to participation of the interested public in procedures of adopting laws, orders and other regulations, the Government has adopted the Code of Practice as guidelines for effective consultations between state bodies and the interested public.

In addition to the above-mentioned provisions, the 2013 Act contains also provisions on measures on radiological safety, on nuclear safety, on quality assurance and on professional competences; radioactive waste and spent nuclear fuel, on response to an emergency and on inspection supervision are also

extensively covered in the 2013 Act. Furthermore, the 2013 Act contains provisions on physical protection of ionizing radiation sources and nuclear installations, on non-proliferation of nuclear weapons, on monitoring the radioactivity in the environment, on reporting and self-assessment obligation (of SORNS), on financial obligations and on penal provisions.

It is worth mentioning that the 2013 Act has several provisions prohibiting operations involving ionizing radiation sources and/or nuclear operations to begin prior to the issuance of the appropriate approval or license from SORNS; furthermore there is a general provision in Article 20 which stipulates that the holder of an approval/license is responsible for the implementation of radiological and nuclear safety measures and bears the costs of their implementation. The IRRS team was of the opinion that such general provisions do not address appropriately the continuity of responsibility where activities are carried out by several persons or organizations successively and are not in line with requirements of the IAEA GSR Part 1.

Legislation (i.e. comprises all acts, regulations, and ordinances) relating to radiological and nuclear safety requires that a licensee establishes a quality assurance programme, although IAEA GS-R-3 requires the establishment of an integrated management system, (quality assurance is just one element of a management system). The 2013 Act does not require the promotion of safety culture. These issues are addressed in the recommendation R1 of this report.

In the national framework on safety certain provisions are missing or are not covered fully in line with GSR Part 1, Requirements 2 and 6 such as: provisions of a graded approach; provisions ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively; provisions on release from regulatory control; provision that stipulates that compliance with regulations does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.

The interface between safety with nuclear security and state system of accounting for, and control of, nuclear material is provided in the scope commensurate with the existing national programme for the nuclear energy use taking into account that no nuclear installations are operated. Refer to Section 5.3 for further details.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: In the national framework on safety certain, provisions are missing or are not covered fully in line with GSR Part 1, Requirements 2 and 6 refer to provisions ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively; provisions of a graded approach; provisions on release from regulatory control; provision that stipulates that compliance with regulations does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.
(1)	**BASIS: GRS Part 1 Requirement 2, para. 2.5. states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *(1) ....* *(3) The type of authorizations that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach….* *(6) Provision for assigning legal responsibility for safety to the persons or organizations*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	responsible for the facilities and activities, and for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively… *(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach…* *(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach…* *(17) The criteria for release from regulatory control…"*
(2)	**BASIS: GRS Part 1 Requirement 6 states that** *"The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.*"
R2	**Recommendation:** The Government should complement the framework for safety with: provisions for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively; provisions related to a graded approach; provisions on criteria for release from regulatory control; provision that stipulates that compliance with regulations does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.

Appropriate recommendation R14 to Government with regards to supplementing the framework for safety by introducing and possibility conducting announced inspection is given in Section 7.1.1.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

As already previously mentioned, SORNS was established as an independent state regulatory body for the regulatory control of the use of radiation sources and nuclear energy. General provisions on independence are included in the Law on State Administration, which provides in its Article 15 that in performing activities within their scope the state administration bodies are independent within the limits of legal authority. As described earlier SORNS has overall authority in the field on radiation and nuclear safety. Where other authorities are also involved in the authorization process the effective allocation of their regulatory functions is prescribed in legislation to prevent any omissions and undue duplication. The responsibilities of SORNS are clearly set down in the 2013 Act and subordinated regulations and ordinances. According to the Act on Organization and Scope of Ministries and Other Central State Administration Bodies, supervision over the work of SORNS is performed by the Government to which SORNS has to report on a biannual basis. The Director General of SORNS is appointed by the Government.

SORNS has been provided with sufficient legal authority to fulfil the statutory obligations for the regulatory control of all facilities and activities in Croatia.

The Croatian Government has ensured that SORNS is effectively independent in its safety related decision-making and that functional separation from entities having responsibilities or interest that could unduly influence its decision-making is ensured.

According to the Act on State Administration System, finances for the work of SORNS as a state administration body are provided in the state budget. This is the only financial resource for the regulatory

body to discharge its assigned responsibilities. The IRRS team was informed that SORNS' budget for 2015 decreased for about 30 % compared to 2014.

Certain regulatory functions of SORNS are not fully implemented due to this reduced budget, for example: inspection of practices throughout Croatia; education and training of SORNS staff; IT support of regulatory activities, including computerization; systematic testing of ionizing radiation and monitoring of radioactive substances in the environment; establishing the integrated management system; development of ordinances, guidelines and internal procedures; servicing and calibration of SORNS equipment; sharing of international operating and regulatory experience and involvement in international activities etc.

Taking into account current regular assignments, as well as upcoming tasks, SORNS is currently, and will be in the future especially, short of staff. Those future tasks are primarily related to the management of radioactive waste and spent nuclear fuel (i.e. establishment and licensing of the Central National Storage facility and reaching common solution for Krško NPP low and intermediate level radioactive waste management and for the spent fuel management), but are also closely related to the preparation and maintaining a comprehensive legal framework, to fulfilment of international obligations and commitments as well as to some other areas of core activities and responsibilities of the SORN. The number of qualified and competent staff dedicated to licensing and inspection is not sufficient, commensurate with the nature and the number of facilities and activities to be inspected.

For the execution of its duties and responsibilities, SORNS must propose its internal organization to the Government based on the Act on Organization and Scope of Ministries and Other Central State Administration Bodies. The Government adopted the Regulation on the Internal Organization of the State Office for Radiological and Nuclear Safety in 2012. This Regulation prescribes an indicative number of positions (49), the organizational structure and description of the responsibilities of SORNS.

The IRRS team reviewed the resources of SORNS needed to carry out and effectively discharge its statutory obligations, both nationally and internationally. The IRRS team noted that staff of SORNS was professional and committed to their work. However, it was also recognized that SORNS faces many challenges, some of them are specifically referred to in this report's recommendations and suggestions. The serious challenges include: increasing the scope of its regulatory activities due to the increasing use of radiation sources, especially in medicine; activities regarding the plans to establish and license a Central National Storage Facility and reaching solution for Krško NPP low and intermediate level radioactive waste management and for the spent fuel management; preparation and maintaining a comprehensive legal framework; fulfilment of international obligations and commitments, just to mention a few.

At the same time, the number of staff of SORNS has decreased and from 2011 to 2014 lost about 60 % of its experienced staff and 20 % of staff overall.

From the number of employees in different services and departments, it appears that there are some organizational units where SORNS statutory obligations are discharged by limited qualified staff, for example licensing, inspection, enforcement, emergency preparedness and response, international cooperation, radioactive waste management and legal affairs. The later one is not needed only for an exercise regarding the preparation of legislation, but also as professional support in the implementation of enforcement policy as well as in licensing and inspection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The Croatian Government has established SORNS as an effectively independent regulatory body, however the resources provided to SORNS are not

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	adequate to perform all of its regulatory responsibilities.
(1)	**BASIS: GRS Part 1 Requirement 3 states that** "*The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.*"
(2)	**BASIS: GSR Part 1 Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
R3	**Recommendation: The Government should provide SORNS with human and financial resources enabling SORNS to completely fulfil its statutory obligations for regulatory control.**

Recommendation R6 to SORNS regarding resources is given in Section 3.1.

Furthermore by the 2015 amendments of the 2013 Act SORNS is responsible to "organize additional professional training and skills refreshment courses on application of radiology safety measures".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The 2015 amendments of the 2013 Act assigned SORNS with the responsibility to "organize additional professional training and skills refreshment courses on application of radiology safety measures".
(1)	**BASIS: GRS Part 1 Requirement 4, para.2.9 states that** *"No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities."*
(2)	**BASIS: RS-G-1.4, Para 2.8 states that** "*The regulatory body should not be responsible for providing training, except for training of its own staff. However, whenever appropriate, the regulatory body should provide guidance in respect of the types of training required, the course content, the duration and level of training, and the assessment of trainees. Training centers and courses dealing with safety and with protection related aspects of nuclear, transport and waste safety may be accredited by the regulatory body or by other professional bodies recognized by the regulatory body.*"
S1	**Suggestion: The Government should consider organizing training and refresher courses in a way that do not compromise effective independence of SORNS.**

In addition to S1, recommendation R19 is given in Section 10 about the responsibility of SORNS.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

The prime responsibility for safety is covered in Article 20 of the 2013 Act, which states that the holder of the approval and the beneficiary shall be responsible for the implementation of radiological and nuclear

safety measures and shall bear costs of their implementation. The IRRS team considered the requirements of the 2013 Act met the IAEA requirement for assigning the prime responsibility for safety.

The legal framework for compliance with regulations in Croatia is provided through the 2013 Act on Radiological and Nuclear Safety and relevant Governmental Regulations and SORNS Ordinances, as described in Section 1.2 of this report. SORNS is entrusted with powers to carry out inspections and assessments within its mandate to satisfy itself licensees have the necessary processes in place to meet their legal obligations. The legal framework does not include the requirement stipulating that compliance with regulations does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety. The appropriate Recommendation R2 is given in Section 1.2.

The IRRS team has observed that SORNS is issuing a relatively large number of licenses for use of ionizing radiation sources. However, the added value for safety with such a practice might not be justified considering the current level of regulatory and human resources. The legislation in force provides that such licenses may be issued for a maximum of five years, so the practice of issuing such licenses for only one year might be changed by introducing other actions of SORNS, as for example inspections.

Further details about the use of a graded approach are described in Sections 5 to 8 and 10 of this report and Recommendations R12, R13 and R17 and Suggestion S5 are given in these sections.

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

SORNS cooperates with several ministries and other administration bodies that have different responsibilities for safety within the regulatory framework:

- the Ministry of Health is responsible for health protection of the public;
- the Ministry of Environmental and Nature Protection is responsible for environmental protection;
- the Ministry of Construction and Physical Planning is responsible for planning of land use and for issuing of construction permits;
- the Ministry of Maritime Affairs, Transport and Infrastructure is responsible for the control of transport;
- the Ministry of Finance is responsible for customs control at the borders;
- National Protection and Rescue Directorate is responsible for emergency planning and response.

The Act on Organization and Scope of Work of the Ministries and Other State Administration Bodies provides (among other ministries and state administrative bodies) in its Article 34 outlines SORNS functions and responsibilities; although the description is rather detailed and prescriptive, SORNS functions and responsibilities are further elaborated and listed in so called “lex specialis”, i.e. in the 2013 Act on Radiological and Nuclear Safety and subsequent regulations and Ordinances, adopted for its execution.

It is worth mentioning that in the 2013 Act only the responsibilities and functions of SORNS are specified; in the licensing process the decisions of SORNS have mainly the form of an approval, which means that in the respective area after the approval, for example for the construction of a nuclear installation (Article 16 of the 2013 Act), the administrative/licensing process continues and the Ministry of Construction and Physical Planning issues, once all other requirements are also fulfilled, must also issue a construction permit, regulated by specific legislation.

SORNS cooperates with the above listed state authorities mainly in the process of adoption of ordinances or drafting of regulations. Although according to the Act on Government, permanent and ad hoc working bodies can be established for giving proposals, opinions, as well as expert explanations about questions in

its scope. The IRRS team was told that no such permanent or ad-hoc body has ever been established by SORNS, except for the commission for drafting the Strategy of disposal of radioactive waste, disused sources and spent nuclear fuel, which was composed of representatives of several ministries and other governmental bodies.

During the joint meeting of the IRRS Team Leader and Team Coordinator with the Vice-Minister of Health and Director General of SORNS, the Vice-Minister of Health demonstrated strong commitment to safety. Recommendations R23 and R24 for the development of their cooperation are given in the Section 11.1.

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

The IRRS team received within the Advance Reference Material (ARM) an explanation that the Croatian Government has established an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events by the Ordinance on the Method of Removal of Radioactive Contamination, Disposal of the Radioactive Source or Undertaking Other Indispensable Measures in Order to Reduce the Damage to People and the Environment or Eliminate Further Threats, Hazards or Damages. The content could not be found in the said Ordinance; on the contrary, the Ordinance governed almost entirely only radiation risks arising from regulated activities or sources, and does not cover the protective actions to reduce undue radiation risk associated with unregulated sources and contamination from past activities.

On the other hand the Regulation on Measures for Protection Against Ionizing Radiation and Interventions in Case of Emergency (OG 102/12) sets up the response system that is applied in the event of the emergencies, which are categorized into five categories. Furthermore the 2013 Act lists the organizations which are, beside SORNS, responsible for making arrangements to protect workers, the public and the environment in situations where unacceptable radiation risks may arise as a consequence of an accident, a discontinued practice or inadequate control over a radioactive or a natural source. SORNS role in such arrangements are prescribed in Article 7 of the 2013 Act as "to ensure expert assistance in the implementation of the Regulation on Measures for Protection Against Ionizing Radiation and Interventions in Case of Emergency".

Appropriate recommendations R35 and R36 for existing exposure situation and remediation are given in Section 11.3.3.

1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

The Republic of Croatia has the obligation to manage radioactive waste and disused radiation sources that have been generated through the 60 years of use of radiation sources in medicine, industry, science, military and public use. The facilities in which this radioactive waste was temporarily stored to date have been closed. Therefore it is necessary to establish a central radioactive waste storage facility as stipulated in the Act on Radiological and Nuclear Safety OG 141/13.

Furthermore, the Republic of Croatia has the obligation to remediate localities where there are naturally-occurring radioactive materials, which requires continuous regulatory supervision. This is addressed in Section 11.3.3.

Also, in compliance with the Act on the Ratification of the Treaty between the Government of the Republic of Slovenia and the Government of the Republic of Croatia, the Republic of Croatia is obliged to physically take over and manage one-half of the radioactive waste and spent nuclear fuel currently stored at Krško Nuclear Power Plan. This is supported by other legislative instruments, such as: the regulation of the status and other legal relations regarding investment, exploitation and decommissioning

of the Krško Nuclear Power Plant and Joint Declaration at the time of signature of the Treaty between the Government of the Republic of Slovenia and the Government of the Republic of Croatia on the regulation of the status and other legal relations regarding investment, exploitation and decommissioning of the Krško Nuclear Power Plant (OG – International Agreements 9/02).

The Regulation OG 44/08 ‘on conditions and method of disposal of radioactive waste, spent sealed radioactive sources and ionizing radiation sources which are not intended for further use’ requires in:

Article 32.

> The owner and/or holder of low and intermediate level radioactive waste, spent sealed radioactive sources or ionizing radiation sources which are not intended for further use may store them in his own storage facility for a period not exceeding 6 months.

Article 33.

> The location for storage of radioactive waste spent sealed radioactive sources or ionizing radiation sources which are not intended for further use (central storage facility) shall be determined by the Government of the Republic of Croatia.

Article 46.

> A spent sealed radioactive source which can be further used or a radioactive source which is not intended for further use must first be offered to another user to include it in another activity, or returned to the manufacturer. If this is not possible, it shall be stored in the central storage facility or land filled.
>
> A leaking spent sealed radioactive source which cannot be further used must be packaged to prevent release of radioactive material and stored in accordance with its properties.
>
> Spent sealed radioactive sources which are not leaking, but cannot be further used shall be disposed in the same manner used for leaking sources after their packaging.

Article 47.

> Low level short lived spent sealed radioactive sources may be stored by the owner in his own storage facility until clearance levels are reached, provided that the total required period does not exceed 3 years.

The above mentioned regulatory requirements are not currently fulfiled because of the absence of an appropriate central storage facility.

On the basis of the existing state in the Republic of Croatia in the area of management of institutional radioactive waste and disused sources, and in the area of managing radioactive waste and spent nuclear fuel from the Krško Nuclear Power Plant, the Strategy for the Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel ('the Strategy') was formulated. The purpose of the Strategy is to determine the goals and establish guidelines for building a national system for the management of radioactive waste, disused sources and spent nuclear fuel.

Promulgation of the Strategy was done by the Parliament. According to this Strategy, the Central National Storage Facility is supposed to be designed, constructed and put in operation in 2016. A set of strategic objectives and guidelines are included prepared within the National Programme, which were developed in accordance with the requirements given in the 2013 Act (Articles 57, 58 and 59). The National Programme is prepared but not yet approved by the Government of the Republic of Croatia.

The selection of locality, development of the basic design of the facility and the preliminary safety assessment are underway.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There is an absence of active central storage facility for radioactive waste, disused sources or orphan sources and foreseen spent nuclear fuel in the Republic of Croatia.
(1)	**BASIS: GSR Part 1 Requirement 10 states that** *"The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel."*
R4	**Recommendation: The Government should implement the provisions for the safe management of radioactive waste in particular with the construction and operation of the Central National Storage Facility in compliance with the Strategy for the Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel.**

1.8. COMPETENCE FOR SAFETY

The formal requirements on competences of all parties assigned with safety related responsibilities (regulatory body, authorized parties/licensees and the organizations providing services or expert advices on matters relating to safety) are ensured by the relevant legislation.

Regarding the professional training for the personnel of SORNS, according to the Civil Service Act, all civil servants are required to regularly improve their knowledge, skills and abilities necessary for performing duties of their workplace and participate in organized educational programmes. Furthermore Ordinance on Internal Organization of the State Office for Radiological and Nuclear Safety prescribes for each working place in SORNS a list of required basic knowledge, skills, abilities and the educational qualifications as well as time of working experience (refer to Section 3.1 for more details).

The basis for requirements for professional competencies of licensees and their workers handling ionizing radiation sources (especially exposed workers) is partially prescribed in Article 47 of the 2013 Act on Radiological and Nuclear Safety while the details are prescribed in corresponding Ordinance issued by the Director General of SORNS. On the other hand similar provision and requirements for licensees and worker in nuclear installations can be found in Article 48 of the 2013 Act and, again, in Ordinance OG74/06.

With respect to the organizations providing services or expert advices on matters relating to safety (authorized professional technical services and authorized nuclear safety experts) the Ordinance on Giving Permissions to the Expert Technical Services to Perform Expert Tasks Related to the Ionizing Radiation and prescribe among other requirements and conditions for authorization also those related to formal education while the Ordinance on Special Requirements which Expert Organizations Must Fulfil in Order to Perform Certain Activities in the Field of Nuclear Safety binds conditions for issuing authorizations only to the fulfilment of organizational, technical and technological requirements, not mentioning education and training requirements.

Based on the 2013 Act (Article 7) one of the responsibilities of SORNS is to develop technical platforms for training curricula and programmes for regular and additional education as well as for refreshment of knowledge in the field of radiological safety. According to the 2015 amendments to 2013 Act SORNS is discharged with another responsibility, i.e. to "organize additional professional training and skills refreshment courses on application of radiology safety measures".

Other responsibilities of SORNS related to the competence building are: to stimulate and support scientific research and development activities, encourage development, statistic and other research in accordance with demands and requirements pertaining to the development of radiological and nuclear

safety in Croatia and to cooperate with international and national organizations (as for example the IAEA) and societies active in the area of radiological and nuclear safety, and appoint its own expert representatives to take part in the work of such organizations and societies or to monitor their work. It was explained to the IRRS team that due to financial crisis and decrease of SORNS budget the support to scientific research and development activities is very limited; the only concrete example of such support is the financial support of SORNS to Faculty of Electrical Engineering and Computer (FER) to participate in USNRC programme of Severe Accident Research and on Thermal-Hydraulic Code Applications and Maintenance.

1.9. PROVISION OF TECHNICAL SERVICES

As mentioned several times before, the legislation in force provides for technical services (i.e. authorized professional technical services) conditions for authorization, scope of tasks and duties, etc.

For the area of radiological safety such services are provided by EKOTEH Dosimetry; Ruđer Bošković Institut; Institute for Medical Research and Occupational Health; and University J.J.Strossmayer; Osijek for different areas as for example: personal dosimetry, environmental monitoring and the calibration of equipment, testing of sealed radioactive sources and / or X-ray devices, etc.

1.10. SUMMARY

The IRRS team concluded that legal and regulatory framework for radiological safety is in place, including the effectively independent regulatory authority – SORNS.

For more strengthened and comprehensive legal and regulatory safety framework, the Government should complement the framework for safety in the areas, as indicated in this Section. Formalization of the national policy and strategy for safety would promote further advancements.

Two additional areas warrant special attention:

- SORNS should be provided with additional staff to completely fulfil tasks within its statutory obligations for the regulatory control.
- SORNS should organize professional training and refreshment courses without compromising its effective independence.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

International co-operation and exchange of operating and regulatory experience on radiological and nuclear safety is important in developing a global safety regime. The IRRS team reviewed the range of international multilateral conventions, bilateral agreements and exchange agreements on events, such as emergency arrangements, with SORNS staff.

SORNS duties, as defined in Article 7 of the 2013 Act on Radiological and Nuclear Safety, include the fulfilment of commitments which Croatia has to assume in according with international conventions, contracts and agreements pertaining to the protection against ionizing radiation, nuclear safety, nuclear damage and the application of protective measures aimed at non-proliferation of nuclear weapons; cooperation is also required with international and national organisations and societies active in the area of radiological and nuclear safety, appointment of Croatian experts taking part in the work of such organisations and societies or monitoring their work as well as coordination of technical cooperation with the International Atomic Energy Agency (IAEA).

Croatia is a contracting party to all major international treaties and conventions ensuring safety in the utilization of nuclear energy and radioactive waste management. It fulfils its international obligations, participates in the relevant international arrangements and promotes international cooperation to enhance safety globally, within available financial resources and human capacities.

Croatia has made a political commitment to follow the guidance of the Code of Conduct on the Safety and Security of Radioactive Sources and has implemented the objectives concerning the facilities and activities under the scope of this code through the 2013 Act and its subordinate regulations and ordinances.

IAEA safety standards are utilized in the preparation of legislation documentation in the field of radiological and nuclear safety. Representatives of SORNS participate in the work of numerous IAEA Safety Standards Committees.

Croatia hosted the Emergency Preparedness Review (EPREV) Mission in 2012 and the Integrated Mission of Programme of Action for Cancer Therapy (imPACT) in 2014.

After the Fukushima accident, Croatia accepted the invitation to join the Nuclear Stress Test in the form agreed with the European Commission. According to the agreement no national report was required on the status of Croatia's national nuclear programme but the Commission expected comments on the Slovenian National Report due to the joint venture between Slovenia and Croatia (NPP Krško) and the Croatian participation in the peer review process.

According to the Act on Radiological and Nuclear Safety, the Director General of the State Office for Radiological and Nuclear Safety shall be obliged to perform a self-assessment of the national legislative framework, and of the competent authorities, at least every 10 years, as well as invite an international audit for important segments of the national legislative framework and competent authorities with the purpose of continuous improvement of the protection against ionizing radiation and nuclear safety. The results of the self-assessment shall be made public. Establishment of the requirement for conducting international reviews and making their results public in the framework of the national law is a notable practice.

In addition to its heavy workload related to regulatory activities, it is a challenge for SORNS to meet its commitments arising from international obligations with the existing staff numbers.

In addition, SORNS must ensure continued capability and competence to be effective in its contribution to international activities.

The IRRS team concluded that the Croatian Government and SORNS effectively fulfils their international obligations, participates in the relevant international arrangements, including international peer reviews, and promotes international cooperation to enhance safety globally.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Since Croatia has no nuclear installations on its territory, no formal operating experience feedback process has been established for events in nuclear installations, and Croatia is not a member of the ISOE and/or participate in international reporting systems (as IRS or WANO).

On the other hand, information should be disseminated in the radiological safety area on abnormal events, incidents, lessons learned and progress achieved in developing legislation. The preparation of SORNS biennial report to the Croatian Government, preparation of national reports and participation on the review meetings in accordance with the Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management is appreciated, but does not address comprehensively the issue of radiological safety.

The 2013 Act contains the obligation of the holder of the approval to inform SORNS of violations its provisions and of its subordinate regulations that threatens the life and health of people (Article 36). Beside this requirement, there are also other provisions related to the reporting obligations of the licensee; but the IRRS team concluded, from the information presented, that there is no process in place in SORNS for acquiring information, analyzing and disseminating such operation and regulatory experiences and for feedback on corrective actions or measures in response to information received.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: SORNS has not established arrangements for analyzing and disseminating the lessons learned from national and international operating experience and regulatory experience.
(1)	**BASIS: GSR Part 1 Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."*
R5	**Recommendation: SORNS should established and maintain process and procedures for analyzing and disseminating the lessons learned from national and international operating experience and regulatory experience to be used by SORNS, other authorities and authorized parties.**

2.3. SUMMARY

The IRRS team concluded that both the Croatian Government and SORNS are active contributors to the global nuclear safety regime and effectively fulfil their international obligations. While the value of international exchange of information is also well recognized, the absence of SORNS documented arrangements for analyzing and disseminating the lessons learned from national and international operating and regulatory experiences was also recognized.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The duties and responsibilities of SORNS as a state administrative body in the area of radiological and nuclear safety are prescribed in the 2013 Act on Radiological and Nuclear Safety and are listed in details in Article 7 of the 2013 Act. These duties and responsibilities cover those that are required by Section 4 of GSR Part 1.

For the execution of its duties and responsibilities SORNS must propose its internal organization of SORNS to the Government, based on the Act on Organization and Scope of Ministries and Other Central State Administration Bodies.

The Government adopted the Regulation on the Internal Organization of the State Office for Radiological and Nuclear Safety in 2012. This Regulation prescribes an indicative number of positions (49), the organizational structure and description of the responsibilities of SORNS.

The Director General of SORNS adopted the Ordinance on Internal Organization of the State Office for Radiological and Nuclear Safety) in 2012 and amended it in 2013. The Ordinance prescribes, among other things, the job description of each position. According to The Ordinance on Measures for Protection Against Ionizing Radiation and Interventions in Case of Emergency, SORNS has additional duties and responsibilities that are dealt with in Section 10 of this report.

Besides the General Affairs Division (as independent service), SORNS is divided into two sectors: Radiological Safety and Nuclear Safety and Inspection. Currently SORNS employs 20 staff, excluding the Director General. In June 2015 two additional employees are expected to join the organization, one in informatics and the other in radioactive waste management. SORNS organizational chart and allocation of staff are in the Appendix VIII of this report.

The IRRS team reviewed the structure and allocated resources of SORNS needed to carry out and discharge its statutory obligations, both nationally and internationally. The IRRS team noted that SORNS staff are professional and committed to their work. However, it was also recognized that SORNS faced many challenges, some of them specifically referred in this report's recommendations and suggestions. As already mentioned in Section 1.3, staff number at SORNS decreased, and from 2011 to 2014 SORNS lost about 60 % of its experienced staff and 20 % of staff as a whole.

Although recommendation was given in Section 1.3 for the Government to provide SORNS with additional resources to perform its functions effectively, the IRRS team believes that SORNS can optimize certain processes and strengthen cooperation between its organizational units and more consistently apply the principle of a graded approach. Recommendations and suggestions for the implementation of a graded approach are given for the authorization, review and assessment and inspection in Sections 5-7 of this report. These recommendations, in particular, propose amendments to licensing of practices involving radiation and use of radiation sources and by doing this diminish daily pressure on SORNS employees.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: SORNS does not have sufficient resources to fully implement a graded approach to discharge its responsibilities and perform its functions effectively**.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 16 states that** *"The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities."*
R6	**Recommendation: SORNS should have sufficient resources and optimize them in order to discharge its responsibilities and perform its functions in a manner commensurate with the radiation risks associated with facilities and activities.**

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY

The IRRS team recognized that SORNS staff has significant experience in the field of radiological safety. The discussions and observations of SORNS' staff performing their activities confirmed they were free from external pressure which could adversely influence their professional judgement. According to its position within the organizational structure of the Government (state administrative body) and with respect to its scope of work, SORNS is neither a promoter nor a user of radiation or nuclear related technologies.

Administrative and regulatory measures on the prevention and resolution of potential conflict of interest in the decision-making process are covered in the legislation, as for example in the Civil Service Act, Act on the Prevention of the Conflict of Interest, Code of Ethics for Civil Servants.

It has to be underlined that no appeal may be filed against decisions taken by SORNS in licensing process (mainly in form of approvals) but an administrative dispute may be initiated. In the 2013 Act an appeal against a first-instance decision issued by an inspector of SORNS was possible to be made to a special commission, whose members were appointed by the Government. However, after the new act amendments of 2015 cancelled this appeal process.

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

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The number of staff positions according to Ordinance on Internal Organization of the State Office for Radiological and Nuclear Safety is 49, but the current number of employees in SORNS is only 20. Based on the information received from SORNS, and described in more details in Sections 1.3 and 3.1 of this report, there is a lack of staff resources. Nonetheless the IRRS team recognized that the staff of SORNS is focused in performing their functions in relation to safety.

Furthermore it must be mentioned that there has been a high turnover of staff in the last few years: in five years 14 employees have left SORNS (retirement, better paid jobs) while only 10 have joined SORNS. New staff lacks the necessary experience. The time needed for familiarizing new staff with their specific work requirements represents an additional burden on the rest of the staff. The IRRS team was informed that Government allows employing only one new employee for two employees who have left.

SORNS staffing is regulated by the process of admission to the civil service in accordance with the provisions of the Civil Service Act and the Regulation on Issuing and Processing Public and Internal Announcements in the Civil Service. The IRRS team found that there is no internal systematic training programme, although the number of staff necessary and the essential knowledge, skills and abilities for

them to perform all the regulatory functions are prescribed (predetermined) in the Ordinance on Internal Organization of the State Office for Radiological and Nuclear Safety where the description of each position in SORNS contains a list of required basic knowledge, skills, abilities and the educational qualifications as well as time of working experience,.

The IRRS team took note that many training opportunities are available to SORNS staff by various international organizations, such as the IAEA and/or international professional associations. For example the IRRS team was informed that SORNS was engaged in the project Europe Aid/130051/D/SER/HR - Strengthening Administrative Capacity of the State Office for Radiological and Nuclear Safety.

Specific needs in the training in public communication were stressed by SORNS management.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: SORNS training needs are not systematically assessed and training plans are not established.
(1)	**BASIS: GS-G-3.1 para. 4.9. states that** *"The organization's training plans should include:* *—The objectives of the organization's training plan;* *—An analysis of any areas not covered and a needs assessment for the training;* *—A description of the training programmes and methods to be employed;* *—The resources necessary and responsibilities;* *—Measurement of the transfer of knowledge (questionnaire, diploma, qualification, accreditation, assessment);* *—….."*
(2)	**BASIS: GSR Part 1 para.4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."*
R7	**Recommendation: SORNS should prepare and implement comprehensive training plans in order to improve knowledge, skills and abilities to perform all the functions and responsibilities.**

Recommendations R3 and R6 concerning resources management (including staffing issues) are also made in Section 1.3 and 3.1.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

As already indicated in Section 1.5 of the report the legislative framework for radiological and nuclear safety does not provide for establishment of an advisory body to the SORNS in relation to its responsibilities and authority. Such body may execute its advisory role on permanent basis within the scope prescribed by the legislation in advance or on ad-hoc basis – on demand. In this connection it is worth mentioning that the Act on Radiological and Nuclear Safety (the one from 2010 as well as the one from 2013) provides for establishment of the Radiological and Nuclear Safety Council. Although the Council was meant as advisory body of the Parliament to perform an assessment of the state of radiological and nuclear safety in Croatia and to monitor the work of the SORNS in the area of

performance of operations pertaining to storage of radioactive waste and disused sources originating from the territory of the Republic of Croatia in the central storage installation, among other functions was also to provide opinions on proposals of acts regulating radiological and nuclear safety and other aspects of radiological and nuclear safety in Croatia. As explained to the IRRS team, although the Council has formally been established in fact it never has met and performed its assigned functions, but with 2015 amendments to the Act on Radiological and Nuclear Safety the Council has been formally abolished.

SORNS strongly relies on the TSOs (authorized professional technical services in the area of radiological safety and nuclear safety experts in the area of nuclear safety).

Article 42 of the 2013 Act provides the basis for SORNS authorization of professional technical services as well as the basis for issuing of the corresponding ordinance where the requirements to be met by TSOs and manner for granting authorization is prescribed. Article 43 provides the similar solution for the authorization of the nuclear safety experts while Article 44 of the same Act provides conditions under which a foreign legal or natural person may be granted authorization. For the time being there is no such foreign legal or natural person authorized.

The tasks pertaining to radiological safety as well as those pertaining to nuclear safety are in most cases not stipulated in the 2013 Act itself but the appropriate ordinances issued by the director of SORNS. The tasks of authorized professional services in the area of radiological safety are prescribed in different regulations and ordinances, as for example Regulation on the measures for protection against ionizing radiation and interventions in emergency cases; Ordinance on authorizations and licenses for use of and movement of ionizing radiation sources; Ordinance on the conditions and measures of ionizing radiation protection for performing operations involving radioactive sources, etc.

There are four authorized professional technical services to perform tasks pertaining to radiological safety (EKOTEH DOZIMETRIJA d.o.o.; Institut Ruđer Bošković; Institut za medicinska iztraživanja i medicinu rada and Sveučilište J.J.Strossmayera in Osijek).

Based on the 2013 Act "expert opinions" of TSO's are on the one hand submitted to SORNS, as part of the application for approvals/licences and on the other hand the applicant for the approval/licence bears the costs for obtaining such opinion, this situation could lead to a possible conflict of interest. To resolve such possible conflict of interest it was explained to the IRRS team that in case SORNS is not satisfied with experts/TSOs' "opinions" or if it deems it professionally or otherwise questionable, it may request second opinion, from an authorized or non-authorized expert/TSO and the associated costs will be later also covered by licenses. Such solution follows form the provisions of General Administrative Procedure Act.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

Formal mechanism of communication between SORNS and licensees on safety related issues is in accordance to the procedures prescribed in the General Administrative Procedure Act (OG 47/09); this Act prescribes general rules that have to be followed by the regulatory bodies in the licensing process, for example: in the course of proceedings parties must be given the opportunity to make a statement on all circumstances, facts and legal issues that are important for resolving the administrative matter (Article 30); Inquiry procedure (Article 51); rules on procedure for resolving administrative matters that includes provision on inquiry procedure and on oral hearing; provision of pre-licencing verification conducted when direct observation by the official person is necessary to establish certain facts or to clarify important circumstances; provisions on the Content of decisions that consists of the letterhead, an introduction, the disposition, the explanation, the instruction on legal remedies, the signature of the official person and the official seal of the competent public law authority.

Furthermore the formal mechanism of communication is prescribed in the 2013 Act on Radiological and Nuclear Safety with respect to inspection.

More detailed description on the review carried out by the team is covered in Sections 5 to 8 of this report.

There are also informal mechanism used for communication between SORNS and authorized parties, i.e. by conducting a professional and constructive liaison through meetings and other open communication. Means of formal and informal communication include: correspondence by mail, fax, e-mail, web-based information and public consultation, as appropriate.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

SORNS's regulatory activities and decision making in licensing process are based on legislation: policies, principles and criteria to be observed in the implementation of core processes of SORNS (e.g. establishment of regulatory requirements, licensing, review and assessment, inspection, enforcement, etc.) as well as general formal procedures for the implementation of SORNS core processes are defined in the Act on Radiological and Nuclear Safety (and regulations and ordinances adopted on the basis of this Act), General Administrative Procedure Act (see Section above) and Civil Service Act.

The formal process to be used when preparing new regulatory requirements or changing existing ones is prescribed in particular by the "Code of Practice on Consultation with the Interested Public in Procedures of Adopting Laws, other Regulations and Acts", which provides that proposing or changing of any kind of legislation (act, regulation, ordinance), the public (expert or other) is actively involved. For that purpose, all drafts and proposals are published on the website of SORNS with the announcement of the period of time for interested public to give their opinions or comments.

The content of the 2013 Act ends with "Transitional and Final Provisions"; one of those provisions (Article 97) stipulates that 21 Ordinances remain in force (provided that they are not contrary to this act) until the entry into force of the new ones (as envisaged in Article 96 of the transitional and final provisions of the same 2013 Act). Some of them (approximately one third) are outdated and have been approved by the Director of the State Office for Nuclear Safety and/or by the Minister in charge of health even before SORNS was established.

Although the 2010 Act had a provision (Article 101) that predicted the adoption of 'new' SORNS ordinances within six months from the day that the Act would enter into force, seven out of twenty ordinances are still in force today. The IRRS team was informed that the majority of those obsolete ordinances are already re-drafted and in the process of being approved.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Most of the ordinances issued by SORNS are outdated; meanwhile 2010 and 2013 Acts have been adopted, which provides the opportunity to establish and approve new ordinances.
(1)	**BASIS: GSR Part 1, para. 4.27 states that** "*Prospective changes in regulatory requirements shall be subject to careful scrutiny, to evaluate the possible enhancements in safety that are to be achieved.*"
S2	**Suggestion: SORNS should consider performing systematic periodic screening/review of radiological and nuclear safety legislation, to ensure keeping regulatory safety requirements complete and up-to-date.**

The IRRS team carried out a review of the core process used by SORNS to ensure consistency and control

of its regulatory activities and especially how SORNS ensures the consistency of regulatory requirements and regulatory decision-making. This was undertaken by the team considering SORNS management system, which is reported in Section 4, and the application of the management system through Sections 5 to 11. Recommendations and a suggestion are given in Sections 4 to 11 to improve the formal regulatory process in order to make it stable and consistent: R10, R11, R12, R16, R17, R21 and S4 and S10.

3.7. SAFETY RELATED RECORDS

In accordance with the existing legislation the requirement on establishing, maintaining and retrieving adequate records are available to both regulatory body (SORNS) and licensees. For example, the 2013 Act on Radiological and Nuclear Safety provides responsibilities and duties of SORNS to keep records on the licenses, approvals, decisions and certificates that are issued within the scope of its authority. These records cover: registers on ionizing radiation sources, holders of approvals for performance of operations involving ionizing radiation sources and nuclear operations, beneficiaries, exposed workers, levels of exposure of exposed workers and levels of exposure of persons subject to medical exposure and of other persons. Furthermore SORNS inspectors are obliged to keep a register of performed inspections.

On the other hand according to the Ordinance on the Measurement of Personal Doses, Examination of Ionizing Radiation Sources and Working Conditions and on Reports and Registers (Official Gazette 41/12 and 89/13) legal and natural persons subject to the application of this Ordinance must report any changes held in the registers and provide supporting evidence to SORNS.

As reported by SORNS ARM report, the Ordinance that prescribes the obligation on record keeping for management of radioactive waste, disused sources and spent nuclear fuel has not been issued yet by the Director General of SORNS. For the time being licensees have to report to SORNS and maintain their own records on spent sealed radioactive sources and ionizing radiation source that are not intended for further use. The data on inventory have to be delivered to SORNS, who also keeps these records.

SORNS also establishes and maintains records on events and non-routine releases. These records are managed by SORNS inspectors in the form of the Register of Performed Inspections. The "register" also includes information on possible ordered corrective measures and on the fulfilment of corrective actions.

Information about the radiation sources and dose registers is provided in the Sections 5.3 and 11.2.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

According to the General Administrative Procedure Act (OG 47/09), public law authorities shall provide licensees (in licensing process) with access to the necessary data and provide them with other announcements, advice and professional help. SORNS is delivering this requirement through its website. As party to Espoo and Aarhus Convention, Croatia incorporated in its legal system all provisions necessary to introduce specific requirements with regards to public (local and neighbors) participation in general and in administrative procedures.

SORNS liaises with other governmental authorities at high level by direct communication between the Director General and his counterparts. Also, according to the Act on State Administration System Ministry, state offices and state administration organizations are bound to mutually cooperate and provide each other expert help, submit information about data for which official registers are kept, align plans of work, etc.

According to the Code of Practice on Consultation with the Interested Public in Procedures of Adopting Laws, other Regulations and Acts in the process of proposing or changing of any kind of legislation (act, regulation, and ordinance), private or public organizations or persons are actively involved. For that purpose, all drafts and proposals are published on the website of SORNS with the announcement of the period of time for interested public to give their opinions or comments.

SORNS provides information on incidents and abnormal occurrences to relevant licensees, governmental bodies, national and international organizations and to the public according to the Regulation on Measures for Protection Against Ionizing Radiation and Interventions in Case of Emergency. See also Section 10.

Part of the proactive information policy of SORNS is also on their website with information on radon as well as information on the location of dangerous sources in Croatia (sealed radioactive sources of Category 1, 2, or 3, as well as Category 4 that are used in industrial radiography, geological research and wells).

There is also some information about the possible radiation risks associated with facilities and activities (including the protection of people and the environment) on SORNS website. According to the Ordinance on the Scope and Content of the Plan and Programme of Measures in the Event of an Emergency and of Informing the Public and Competent Bodies, the applicant shall make information available to the public about its practice involving ionizing radiation sources and the possible risk for the population and the environment, and regarding important facts from his plan and programme. The information contains: basic data about the applicant, simple description of the activity and risks associated therewith, simple description of the possible emergencies and consequences that could arise for employees, the population, the space and the environment, an overview of planned measures for the elimination and/or mitigation of consequences of emergencies, and actions the population should undertake in the event of an emergency with possible consequences for people and the environment outside the space controlled by the applicant, refer to Section 10 for more details.

Other information is published on SORNS website, in accordance with Article 10 of the Act on the Right of Access to Information.

3.9. SUMMARY

The IRRS team concluded that SORNS as a regulatory body perform its functions in a manner that does not compromise its effective independence and meets the safety requirements of the IAEA on effective independence. However the necessary human and financial resources are not always provided by the Government (see Section 1.3).

The duties and responsibilities of SORNS as a state administrative body are prescribed in the legislative framework and to large extend cover those that are required under Section 4 of GSR Part 1.

Main challenges for SORNS to be addressed related to:

- managing its resources to discharge its responsibilities and perform its functions in a manner commensurate with the radiation risks associated with facilities and activities, i.e. a graded approach;
- preparing and implementing comprehensive training plans to improve knowledge, skills and abilities of all staff to perform all their regulatory functions.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

Requirement 19 of the GSR 3, Part 1 defines that "the regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement".

SORNS has not systematically developed a management system in accordance with the requirements of the IAEA safety standard GS-R-3, that brings together in a coherent manner all the requirements for managing the organization. Only some parts of SORNS management system are documented and are aligned with the requirements of the IAEA safety standard GS-R-3. SORNS performs activities mainly in accordance with the requirements for managing state administrations (e.g. management processes) defined in laws and regulations of the state administration on documentation, planning, human and financial resources, etc.

As defined in ARM report, SORNS is aware of the importance of an integrated management system. In long term SORNS has plans for implementation of ISO 9001 and adoption of this very document as a management system which is in line with the IAEA safety standards considering integrated management system. The requirement for establishment and implementation of the management system is defined in the SORNS strategic plans for the period 2014 – 2016 and 2015 – 2017 respectively "as Quality Assurance through ISO certificates". However, the strategic plans do not foresee the introduction of integrated management system but only quality assurance that represents only one part of the management system.

ARM self-assessment report describes, that SORNS management does not promote a strong safety culture. Also the IRRS team noted that SORNS management system does not provide structure and direction in a way that permits and promotes the development of a strong safety culture as defined in IAEA safety standards related to management systems. However SORNS performs some activities which could be the basis for promotion of the safety culture e.g. training, information sharing etc. Some elements of safety culture are found as well in:

- "Civil Servant Act"; according to the "Civil Servant Act" civil servants are obliged to perform their duties in accordance with the description of the workplace and they are prohibited to abuse their authorities.
- "Code of Ethics for Civil Servants" according to the code a representative for ethics is nominated by the Director General, and is responsible for receiving complaints related to "Code of Ethics for Civil Servants" from SORNS employees and other interested parties".

In the "Civil Servant Act", and in the "Code of Ethics" it is strongly stressed to avoid the conflict of interests.

Additionally all SORNS employees are periodically informed about the requirements of the "Civil Servant Act" and "Code of Ethics".

As defined in the ARM's report, SORNS has not applied graded approach in the performance of its activities. However, there are some elements of graded approach in place, found e.g. in enforcement process. SORNS did not appear to utilize a graded approach consistent with GS-R-3 and GS-G-3.1. SORNS has not developed grading process which determines the extent of the application of the requirements of the management system to the products and activities. SORNS use of the graded approach does not incorporate complexity, significance, hazards and the magnitude of the potential impact (risks), and possible consequences if a product fails or an activity is carried out incorrectly. Graded approach is often defined on the basis of an expert opinion.

It was recognized that the current management system has not been adequately documented. IAEA Safety Standard GS-R-3 requires that the documentation of an integrated management system at least consists of:

- the policy statements of the organization;
- description of the management system;
- description of the structure of the organization;
- description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;
- description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.

SORNS has defined mission and vision but has not defined values. Goals and organizational structure of the organization are defined in the Strategic Plan. Functional responsibilities, accountabilities and levels of authorities are defined in the "Regulation on Job Classification in the Civil Service" and in the "Internal Organizational Rules of SORNS". Other required documentation of the management system is limited to the consideration of legislation, e.g. the "Law on Archives and Archival and Regulations" which defines the protection and preservation of archives and records of SORNS for management and supporting processes and the "Act on Radiological and Nuclear Safety" for SORNS key processes.

The IRRS team noted that an implementation plan for the establishment of the management system was not in place, yet. SORNS may consider performing gap analyses to find out the area that should be considered and to define the priorities for implementation of the management system.

Above mentioned shortcomings are addressed within the recommendation R9 and suggestions S3 and S4.

4.2. MANAGEMENT RESPONSIBILITY

SORNS has defined the senior management, which consists of the Director General, Heads of Sectors, Heads of Services, and Heads of Departments.

The Director General has an overall responsibility for the management system, i.e. has the power to decide on the management system's implementation. Functional responsibilities by the Director General and all other persons in the regulatory body are arranged hierarchically as defined in SORNS organizational scheme. However, it is noted that SORNS senior management does not have the ultimate responsibility, yet for ensuring that the management system is established, implemented, assessed and continually improved in accordance with GS-R-3.

Means to collect and address some of expectations of interested parties and to communicate with interested parties are described in more detail in Section 3.8 of the report. SORNS communicates to governmental authorities. According to the "Act of State Administration System" organizations are bound to mutually cooperate and exchange information. In the process of proposing and changing of any kind of legislation, public or private organization or persons are actively involved. For that purpose all drafts and proposals are published on the website of SORNS with the announcement of the period of time for interested public to give their opinions or comments. SORNS systematically collect information and opinions on proposed legislation. There are no special meetings organized to spread the new requirements to potential applicants.

SORNS is always open for communication to the interested parties and to the public. SORNS has nominated a person in charge to deal with public according to the Croatian law on the "Freedom of Information". Information and opinions gained are not collected in a systematic way e.g. information related to satisfaction of the interested parties including SORNS employees.

The competences of SORNS are defined within Croatian legislation such as the "Regulations on Internal Organization of the State Administration Bodies", "Regulation on the Internal Organization of SORNS" and "Ordinance on Internal Organizational Rules of SORNS". The IRRS team noted that SORNS has not developed and disseminated through the organization a documented set of internal policies i.e. quality policy, safety policy, that are the basis for establishing of the management's plans, objectives and priorities with the regards to safety, health, environment, security, quality and economic considerations.

SORNS management is responsible for developing the "Strategic Plan", "Annual Plan" and other subordinates plans for provision of resources. The "Strategic Plan" includes as well numerical indicators for measuring the performance of activities. Realization of the "Strategic Plan" is checked twice a year; meanwhile the "Annual Plan" is checked once a year. Every year a new strategic plan is prepared considering the achievements of the goals of previous strategic plan. If the goals of the "Strategic Plan" or the "Annual Plan" are not reached SORNS introduces some corrective actions but usually these are not recorded. SORNS has also prepared a list of all obliged reports with defined responsible person and due-date.

The above mentioned shortcomings are addressed with the recommendation R9 and suggestions S3 and S4.

An individual who is responsible for coordinating the development, implementation and maintenance of the management system and who is reporting directly to the Director General and senior management has not been officially appointed. SORNS' employee who is taking care of the management system is mainly involved in management processes and in supporting processes. The IRRS team noted that the employee has not an overall picture of SORNS' management system and of all the processes performed by SORNS. The IRRS team recognized that the employee is also not involved in the key processes and procedures such as licensing, inspection, enforcement, emergency preparedness, etc.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The staff in charge of coordinating the development, implementation and maintenance of the management system and reporting directly to the Director General and senior management has not been officially appointed.
(1)	**BASIS: GS-R-3 para. 3.13 states that** *"An individual reporting directly to senior management shall have specific responsibility and authority for:* *—Coordinating the development and implementation of the management system, and its assessment and continual improvement;* *—Reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement;* *—Resolving any potential conflicts between requirements and within the processes of the management system.*
R8	**Recommendation: SORNS should appoint an individual with the authority to coordinate and develop the integrated management system and to raise issues relating to the management system to the senior management.**

4.3. RESOURCE MANAGEMENT

SORNS Director General and senior management have a responsibility that the resources which are essential to the implementation of the management system and the achievement of the organization's objectives are identified and made available. SORNS proposes budget and recruitments needs according

to the limits posed by the Ministry of Finance and the Ministry of Public Administration, respectively. The proposition of the budget is prepared on the basis of internal inputs of SORNS senior management in the framework of limits and coordinated on internal meetings. The proposed budget is in line with SORNS strategic plan for the next 3 years, as well. Budget requests and recruitments needs are submitted for approval to the Government on annual basis. The number of staff necessary and the essential knowledge, skills and abilities are prescribed in the "Regulation on the Internal Organization of SORNS" and in the "Ordinance on Internal Organizational Rules of SORNS". However, required financial and human resources for the moment are not fully provided due to the restriction in state budgeting and employment. The appropriate recommendation R3 is given in Section 1.3.

According to the "Civil Servant Act" special educational programmes exist for civil servants employed in the state administration bodies. Every civil servant is obliged to pass the state exam. Also special independent programmes can be organized by the state regulatory bodies. SORNS performs such in-house trainings provided by senior management on relevant topics (general and specific) for new staff.

The assessment of performed work of civil servant is done once a year. This assessment is in a way also a basis for future trainings and career development of the employee; however a systematic approach towards training and career development is not used as a tool, even prescribed in "Civil Service Act".

The IRRS team noted that training process is not systematically developed. Common training plans are not systematically established, documented and evaluated in order that planned trainings are actually aimed to improve specific knowledge related to nuclear and radiological safety. Training issues are captured in more detail in Section 3.3. See also recommendation on management of training R7 in Section 3.3

The systematic approach to the knowledge management does not exist.

SORNS has defined the working environment necessary for work to be carried out in a safe manner in the document "The assessment of risks for jobs in SORNS", July 2014. In 2015 the training of each employee regarding this document is planned.

Above mentioned shortcomings are addressed within the recommendation R9 and suggestions S3 and S4.

4.4. PROCESS IMPLEMENTATION

SORNS processes are not defined in accordance with the requirements of IAEA safety standard GS-R-3. The key processes implemented by SORNS are listed in the "Act on Radiological and Nuclear Safety", namely establishment of regulatory requirements, licensing, review and assessment, enforcement, etc. The description of activities related to documentation, planning, human resources, monitoring etc. is defined within the framework of the "Civil Service Act" and different regulations on state administration.

SORNS has not developed internal procedures related to the key regulatory processes except the internal procedure for the inspection process which was documented recently but has not been approved, yet.

According to the suggestion from Section 7.1.2 some improvement of the procedure is still needed. See recommendation R15 in Section 7.1.2.

According to the IAEA Safety Standard GS-R-3 the following generic processes shall be developed in the management system:

- control of documents;
- control of products;
- control of records;
- purchasing;

- communication;
- managing organizational change.

The process for the control of documents and records which enables an appropriate and correct use of documents is documented in the "Regulation on record management" and some internal SORNS procedures such as "Ordinance on the Protection and Preservation of Archives and Records".

SORNS ensures that the products of regulatory activities meet expectations and applicable requirements through regulations related to state administration.

Considering national "Public Procurement Act", SORNS ensures that suppliers are selected on the basis of specified criteria that their performance is evaluated, the procurement documents are specified, and requirements for reporting and resolution of non-conformances are defined. SORNS has developed its own procedure related to procurement activities in a form of instructions "Instructions on Implementation of Proceedings of Procurement of Goods and Services to Estimated Value 200.000kn and Procurement of Works to 500.000 kn".

Internal communications are performed through different channels, such as intranet, emails, internet, meetings and notice board. The meetings reports of senior management are published on intranet, as well.

The organizational changes are made in accordance with the requirements of the "Civil Servant Act". An additional procedure for managing organizational changes which requires that organizational changes should be evaluated and classified according to the importance to safety and that each change should be justified is not in place.

The IRRS team noted that a general overall process map that defines the following does not exist:

- management processes, key processes and supporting processes;
- sequence and interaction among processes;
- process owners;
- process measurement criteria.

However, according to the requirement of the Ministry of Finance and the Ministry of Public Administration the business processes, which can later be used as a basis for developing a process map, are under preparation.

The IRRS team noted that there is no strong cooperation between performers of different processes especially between inspection process and authorization process. In order to strengthen the key regulatory functions SORNS should consider paying special attention to process interactions and strong cooperation among different performers of the processes especially those who perform authorization activities and those who perform inspections. See recommendation for resource management R6 in Section 3.1.

Above mentioned shortcomings are addressed within the recommendation R9 and suggestions S3 and S4.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Measurement, assessment and improvement process has not been introduced because SORNS has not established documented management system, yet.

However some elements of the management, assessment and improvement process are present; i.e.:

- Review and approval of SORNS output documents in accordance with defined SORNS responsibilities and competences which is done hierarchically;
- SORNS has performed self-assessment considering SARIS. The findings from SARIS self-assessment should be implemented in accordance with the proposed SARIS action plan;

- Internal controls on managing SORNS are provided by governmental service two or three times a year; however internal audits in a sense of GS-R-3 are not introduced;
- Management system reviews are performed for some parts of management system e.g. reviewing annual and strategic plans; however, management system reviews are not formally and systematically conducted at planned intervals.

SORNS does not have arrangements for:

- Independent assessments (internal and external audits);
- Management system reviews;
- The management of non-conformances, preventive and corrective actions;
- Improvements on the bases of preventive and corrective actions.

Above mentioned shortcomings are addressed within the recommendation R9 and suggestions S3 and S4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: SORNS management system is not in line with the requirements of the IAEA safety standards related to an integrated management system. SORNS management system is not documented in accordance with the IAEA safety standard GS-R-3. The strategic plan only covers quality assurance.
(1)	**BASIS: GSR, Part 1, Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement…"*
(2)	**BASIS: GS-G-3.1 para. 2.24 states that** *"Senior management should prepare a plan to achieve full implementation of the management system….."*
R9	**Recommendation: SORNS should develop an integrated management system in line with IAEA safety standard GS-R-3.**
S3	**Suggestion: SORNS should consider revising its strategic plan to expand the requirements on management system from the quality assurance programme to the integrated management system.**
S4	**Suggestion: SORNS should consider preparing the plan for establishment, development, and implementation of an integrated management system where the priorities are stressed out such as defining responsibilities for the management system, defining key processes related to inspection, licensing, etc. and defining the interactions among the processes.**

4.6. SUMMARY

Elements of SORNS management system are defined in different laws and regulations and some internal procedures. "Act on Radiological and Nuclear Safety" determines SORNS key processes namely, establishment of regulatory requirements, licensing, review and assessment, enforcement, etc. Laws and regulations on state administration define management system elements on documentation, planning, human resources monitoring, etc. The established internal procedures are mainly administrative nature. However, SORNS has not established a documented integrated management system in accordance with

safety standard IAEA GSR Part 1, Requirement 19 and additional requirements defined in the IAEA standard GS-R-3. The action plan of ARM SARIS report foresees the establishment and implementation of management system that meets all requirements.

5. AUTHORIZATION

5.1. GENERIC ISSUES

According to the Article 7 of the Act on Radiological and Nuclear Safety the State Office for Radiological and Nuclear Safety (SORNS) is the competent and state administration body for activities pertaining to radiological and nuclear safety, which include authorization activities. According to the Article 9 of the same Act it is stated clearly that "Operations involving ionizing radiation sources shall not begin prior to the issuance of the approval by SORNS".

The authorization process is defined in more detail in the Ordinance on authorizations and licenses for use of and movement of ionizing radiation sources. The authorization process established by SORNS consists of two steps. As a first step SORNS issues an Approval for performance of operations involving ionizing radiation sources (Licence for practice) to a legal or natural person, a state administration body, or to any body of a local or regional self-administration unit for performing specific practice. For the first time, a licence for practice is issued for a period of 5 years. Renewing the licence for practice may be issued for a maximum period of 10 years, depending on the type of ionizing radiation source and the practice, as well as the risk associated with this practice. The second step is Licence for use of the ionizing radiation source. Once a licence for practice is obtained, the licensee may ask for a licence for use of ionizing radiation source, one for each source (except for smoke detectors and unsealed sources for which a "group licence" is issued). This licence for use is issued for only 12 months.

A licence ceases to be valid in the following cases:

- after major repair work, alterations or replacement of parts, which may significantly affect the conditions of the ionizing radiation generation, and before recommencement of use;
- before commencing use at a new location, if the ionizing radiation sources have been relocated from one place to another;
- after each building intervention or change of intended use of the premises accommodating the source of ionizing radiation, which might alter the requirements for protection against radiation protection inside and outside those premises.

In such cases licensees will be required to submit to SORNS an application for a new licence for use of ionizing radiation source.

According to the Ordinance on authorization in the case of modifications to the conditions under which the licence for practice was issued, the licensee must notify SORNS in writing within 15 days from the date modifications take place and submit evidence thereof. After receipt of the notice SORNS must record the information related to the modifications in their central register and issue a certificate to the licensee to this effect, if requested by licensee.

According to the 2013 Act, import, export, transport and transit of ionizing radiation sources, special equipment, radioactive waste, spent nuclear fuel and disused sources may be carried out by legal and natural persons on the basis of an approval or a licence issued by SORNS. The legal and natural persons may perform transport or transit if they meet the requirements stipulated by this Act and by its subordinate regulations, as well as the requirements stipulated by Acts regulating transport of dangerous goods and their subordinate regulations and for transport at the sea, the requirements stipulated by the acts and their subordinate regulations regulating maritime affairs. The approval or licence related to transport is issued for a maximum of six months.

Since SORNS is the only regulatory body responsible for authorization in the field of radiation safety, there is no conflict or overlap with other governmental authorities. Cooperation is established with the

Ministry of Construction, since that Ministry is responsible for issuing a construction licence. Consent that facility is adequate is however issued by SORNS. Cooperation is established with the Ministry of Interior regarding the approval of the security plan of the applicant, which is one of the documents requested for the authorization of practices involving Category 1, 2 and 3 radioactive sources.

At the moment, four SORNS employees are involved in authorization, review and assessment activities. According to the Civil Service Act, all civil servants are required to regularly improve their knowledge, skills and abilities necessary for performing their duties and to participate in organized educational programmes. The IRRS team was informed that majority of the authorization staff did not go through special training related to authorization in radiation protection field and only rely on their own knowledge and experience (see recommendation R7).

According to the 2013 Act, tasks pertaining to radiological safety shall be performed by professional technical services (TSO) authorized by a decision issued by SORNS, also based on the "Ordinance on Giving Permissions to the Expert Technical Services to Perform Expert Tasks Related to the Ionizing Radiation (OG 72/11)". A professional technical service that complies with the requirements set out in this Ordinance must submit its authorization request for these professional tasks to SORNS. SORNS must render a decision authorizing professional technical services to carry out certain professional tasks for protection against ionizing radiation. The decision must be issued for a period corresponding to that of the validity of the accreditation certificate, in accordance with the requirements of the HRN EN ISO/IEC 17025 standard, or for a maximum of five years. SORNS must withdraw the authorization of a TSO if it has been established that the requirements pursuant to which the authorization was granted are not met.

Tasks for which TSO may be authorized are as follow:

1. measurement of personal dose of external irradiation of exposed workers, apprentices or students undergoing training or education for working with ionizing radiation sources;
2. measurement of personal dose of internal irradiation of exposed workers, apprentices or students undergoing training or education for working with ionizing radiation sources;
3. testing X-ray sets, accelerators and any other apparatuses emitting ionizing radiation, and providing opinions including risk assessments based on measurements and calculations;
4. testing sealed radioactive sources and apparatuses with sealed radioactive sources, and providing opinions including risk assessments based on measurements and calculations;
5. testing open radioactive sources and providing opinions including risk assessments based on measurements and calculations;
6. testing the premises where sources of ionizing radiation are used and preparing documents that demonstrate whether the premises concerned comply with the prescribed requirements for protection against ionizing radiation;
7. testing and monitoring types and activities of radioactive substances in the air, soil, sea, rivers, lakes, ground waters, precipitation, drinking water, foodstuffs and general use products; and
8. testing the concentration of radon and radon progeny in the air.

It is clear that a TSO has an important role in the licencing process. One of the documents included in a licensee's application is the TSO's opinion on compliance with the conditions for protection against ionizing radiation for the workplace where the ionizing radiation source will be used or in exposed areas. In addition, risk analysis is a very important document submitted by user, which must be verified by a TSO. In case of practices which involve use of ionizing radiation, but with no exposed workers, TSO's opinion must state that the worker's workplace is not in an exposed area. Prior to issuing a licence for use of ionizing radiation source, the source must be tested by a TSO and its report enclosed with the application.

Furthermore, TSOs are engaged by SORNS for carrying testing and monitoring types and activities of radionuclides in the environment, drinking water, food, feed, general use items, residential and working places. In addition, preliminary determination of the facility environmental status, facility environmental monitoring and final determination of the facility environmental status must be carried out only by a TSO, in this case, engaged by the user, not by SORNS.

According to the Article 36 of the Act on Radiological and Nuclear Safety the holder of the licence and the beneficiary are obliged to appoint a person responsible for protection against ionizing radiation (RPO). According to the Article 8 of the Ordinance on the education required for handling ionizing radiation sources and the application of measures for protection against ionizing radiation, it is defined that RPO must undergo special training in the implementation of measures for protection against ionizing radiation as part of their qualification or through additional training organized and provided by the Institution, as well as refresher courses in the implementation of measures for protection against ionizing radiation every five years.

SORNS maintains records of licensees in respect to their radioactive sources, with a clear indication of the type(s) of radioactive sources that they are licensed to use, according to the Ordinance on measurement of personal doses, examination of ionizing radiation sources and working conditions, and on reports and registers. SORNS also maintains records of the transfer and storage of those radioactive sources.

SORNS has the authority to obtain all information necessary from an applicant for an authorization, including amendments and additional material related to the submitted documentation, as well as other documents during the authorization process. Regulatory inspection is not involved in any activities from the authorization process, and authorization staff do not visit applicants to confirm the validity of the submitted documents.

SORNS may withdraw the licence for practice involving ionizing radiation sources if an inspector finds that the licensee does not fulfil the requirements prescribed by the 2013 Act and its subordinate legislation. SORNS may withdraw the approval for performance of operations involving ionizing radiation sources or the licence for use of ionizing radiation sources if it has established that the licensee or beneficiary does not meet the requirements prescribed by the Act on Radiological and Nuclear Safety or its subordinate regulations and ordinances.

Guides for different activities involving radiation sources in support to the requirements of the Ordinance on authorizations are not developed (see suggestion S9). However, annexes to this Ordinance provide the format and content of the documents to be submitted by the applicant in support of an application for authorization.

The IRRS team has concluded that the authorization process established by SORNS is not commensurate with the radiation risk associated with facilities and activities, in accordance with graded approach. Notification, as a first step in the application process is not defined; therefore an application must be submitted to SORNS on pre-defined forms. The applicant is required to demonstrate safety in support of the application for authorization of a facility or an activity, including:

- examination of medical surveillance of exposed workers, apprentices and students trained and educated to work with ionizing radiation sources;
- measurement of personal doses of exposed workers and availability of data on the monitoring results to the exposed workers;
- training on the application of measures for protection against ionizing radiation for exposed workers;

- training on the handling of ionizing radiation sources for workers who handle ionizing radiation sources.

Additionally, the following documents must be submitted with the application:

- extract from the commercial court register or a written extract from another appropriate register establishing the legal status of the applicant;
- decision on the appointment of the person responsible for protection against ionizing radiation;
- an authorized TSO's opinion in compliance with the conditions for protection against ionizing radiation for each room where the ionizing radiation source will be used or which are considered exposed areas;
- description of the purpose and method of using the radioactive source;
- risk analysis, prepared in accordance with Annex XVI of the Ordinance on authorization, also verified by an authorized TSO;
- decision on establishment and implementation of measures for protection against ionizing radiation prepared in accordance with Annex XV of the Ordinance, etc.

Approval of the on-site emergency plan and programme is a prerequisite to the authorization of use of ionizing radiation sources only in relation to practices involving dangerous sources as elaborated in Section 10.1.

According to the Act on Radiological and Nuclear Safety the licence shall be granted or denied by a decision against which no appeal may be filed, but an administrative dispute may be initiated. The procedure for an administrative dispute is prescribed in the Act on Administrative Disputes.

In 2014, SORNS issued: 274 licences for practice, 2186 licences for use of ionizing radiation sources, 14 procurement licences, 32 import permits, 12 export permits and 22 permits for shipments of radioactive substances between Member States.

The IRRS team was notified that many licensees which were authorized previously have not renewed their authorization after the new period (5 years) of licence validity was introduced into legislation. SORNS explained that the main reason for this situation is that previously issued licences had no periods of validity specified into licencing conditions and that deadline for renewal of those licences expired before only two months. It is expected that this issue will be resolved after the inspection programme becomes effective.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Notification as a document submitted to SORNS by the applicant to notify an intention to carry out a practice, and criteria when notification only is sufficient, are not defined under the existing legal framework.
(1)	**BASIS: GSR Part 3 Requirement 3 para. 2.30 states that** "*The regulatory body shall establish a regulatory system for protection and safety that includes [8]:(a) Notification and authorization;*
(2)	**BASIS: GSR Part 3 Requirement 7 states that** *"Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body, as appropriate, a notification or an application for authorization."*
(3)	**BASIS: GSR Part 1 Requirement 23 states that** *"Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	those facilities and activities that are not either explicitly exempted or approved by means of a notification process."
R10	**Recommendation: The Government should establish a regulatory system for protection and safety that includes notification process, with criteria for when notification only is sufficient.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The authorization process established by SORNS is implemented as a two steps licencing process in forms of a general Licence for practice and additionally, for each particular source of ionizing radiation every year a Licence for use of ionizing radiation sources, which is not commensurate with the radiation risk associated with facilities and activities, in accordance with graded approach. As a result this approach does not lead to the optimization of resources.
(1)	**BASIS: GSR Part 1 Requirement 2, para. 2.5 states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *(3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;*
(2)	**BASIS: GS-G-1.5, para. 3.23 states that** *"The Basic Safety Standards apply the terms notification, and authorization by registration or licence to indicate broadly an appropriate type of control based upon the levels of risk or complexity associated with non-exempted practices, notification being applied to the lowest level of risk or complexity and licence to the highest…"*
S5	**Suggestion: SORNS should consider developing a system of authorization commensurate with the radiation risks associated with the facility or activity taking into account a graded approach.**

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The legislative framework of the Republic of Croatia in the area of management of radioactive waste, disused sources and spent nuclear fuel is currently comprised by the Act on Radiological and Nuclear Safety OG 141/13, 2 regulations and 19 ordinances.

The 2013 Act states that the operation involving management of radioactive waste, disused sources and spent nuclear fuel shall be licensed. A licence is required for radioactive waste management that includes treatment, conditioning, handling, transport, storage and disposal excluding transport outside the area of management. The Article 50 of the 2013 Act OG 141/13 deals with the approvals for the performance of operations involving the management of radioactive waste, disused sources and spent nuclear fuel. No such operation can commence before the approval is issued by SORNS. The approvals are granted for a maximum period of 10 years. Related to the Article 26 of the 2013 Act OG 141/13, for radioactive waste

and nuclear facilities appropriate decommissioning arrangements have to be established (where applicable) before the operational license is granted.

The principles, classification, release and exemptions from supervision, the manner of recording and managing radioactive waste and disused sources are defined in detail in the Regulation OG 44/08.

In the Republic of Croatia there are no nuclear facility in operation or in the process of decommissioning, no research reactor. There are only two facilities for the purpose of storage of radioactive waste originating from medicine, industry, science, education and from the past public use. Both facilities are currently closed and not in position to accept new waste.

According to the Strategy for the Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel Central National Storage Facility is supposed to be sitting, designed, constructed and put in operation within two years. After the Central National Storage Facility is established, sources and radioactive waste from two institutes (Section 7.2) will be conditioned, repacked and transferred to this location (see recommendation R4 in the Section 1.7).

In compliance with the Strategy the Act on Radiological and Nuclear Safety which is the basic legislative act in the area of the safety of radioactive waste management and spent fuel has been amended. Further requirements from the view of management of radioactive waste and spent nuclear fuel were newly defined or changed.

The Regulation OG 44/08 needs to be replaced in line with the provisions of the 2013 Act.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The Act on Radiological and Nuclear Safety stipulated formally requirements for licensing the site, construction, operation and closure radioactive waste management facility without specific requirements. The requirements described in existing regulation OG-44/08 are not sufficient for all radioactive waste management activities described in the 2013 Act and the regulation is not in line with the provision of the 2013 Act. The new Ordinance prescribed in the 2013 Act (Article 49 (8) and Article 50(4)) is still not drafted.
(1)	**BASIS: GSR Part 1 Requirement 23 para 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."*
(2)	**BASIS: SSR - 5 Requirement 2 states that** *"The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met."*
R11	**Recommendation: SORNS should develop and approve Ordinance regarding the detailed requirements for licensing the site, construction, operation and closure radioactive waste management facility as prescribed in the 2013 Act.**

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

All that was mentioned above in Section 5.1 for general issue of authorization is applicable to the authorization of radiation sources facility and activities.

Article 5 of the Ordinance on authorizations, specifies that the licence is required for the following practices involving radioactive sources: manufacture of radioactive sources, use of radioactive sources, import and export of radioactive sources, transport of radioactive sources, service and repair of radioactive sources and devices with installed radioactive sources, assembly or installation, and dismantling of radioactive sources and devices with installed radioactive sources, sale and any other type of movement of radioactive sources and remediation.

According to the Article 11 of the Ordinance the licence is required for the following practices involving X-ray units, accelerators or other electrical devices generating ionizing radiation: manufacture, use, import and export, installation and dismantling, service and repair, sale and any other type of movement.

The Government of Croatia has adhered to the Code of Conduct on the Safety and Security of Radioactive Sources and implements its objectives in the facilities and activities under the scope of the code through the Act on Radiological and Nuclear Safety and its subordinate legislation adopted on the basis thereof.

According to Article 33 of the 2013 Act, a licensee is required to set up and implement a quality assurance programme as well as to conduct quality control. The quality assurance programme shall be set up, implemented and maintained pursuant to the instructions laid down in Annex IX, which is an integral part of the Ordinance on Conditions and Measures for the Protection Against the Ionizing Radiation in Performing the Activities with Radioactive Sources.

Requirements for security issues are an important part of any activity dealing with radioactive sources and are established in the 2013 Act. During the performance of its operations, the licensee is liable for the implementation of security measures for ionizing radiation sources and must bear the costs of its implementation. The manner of implementation is prescribed in detail by Ordinance on Physical Protection of Radioactive Materials, Nuclear Materials and Nuclear Objects. The licensee has to develop and implement a Security Plan for Category 1, 2 and 3 radioactive sources. Every plan must be specific to the licensee and must specify in detail security measures to deter, detect and delay the unauthorized access to, or the theft, loss or unauthorized use or removal of radioactive sources or nuclear materials during all stages of management of the facility/activity. For each individual plan user has to obtain consent which is issued by SORNS and later by the Ministry of Interior.

Croatia has established a national register of radioactive sources, maintained by SORNS, and includes radioactive sources of all categories, including Category 1 and 2 radioactive sources that are described in Annex 1 of the Code of Conduct. Information relevant to the source registry is regularly updated.

SORNS maintains detailed records of the licensees' radioactive sources, including type of radioactive sources that they are licensed to use. SORNS also maintains records of the transfer and storage of radioactive sources on termination of authorizations. After any transfer or disposal for storage, SORNS enters new data regarding source into the register.

Although there is no requirement that licensee must conduct inventory controls on a regular basis, it is written that licensee must keep the records on radioactive sources for at least 10 years after the termination of use. Minimal content of these records is given in Article 35 of the Ordinance on measurement of personal doses, examination of ionizing radiation sources and working conditions, and on reports and registers. Additionally, for high-activity sealed radioactive sources (as defined by EU HASS Directive), the licensee is required to keep more records, according to Article 31 of the Ordinance on the

conditions and measures of ionizing radiation protection for performing operations involving radioactive sources.

Reuse or recycling of radioactive sources is encouraged, according to Article 26 of the Ordinance on Permissions and Allowances for the Application and Transport of the Ionizing Radiation Sources. A radioactive source which is no longer intended for use must initially be offered to another beneficiary for the purpose of using it in another practice or it must be returned to the manufacturer. If this is not possible, it must be stored or its disposal will be ensured pursuant to a specific regulation.

Exemptions from the requirement to obtain the license for practice and the licensee for use of radioactive sources and electric devices generating ionizing radiation is based on the Article 11 of the 2013 Act and more detailed criteria defined in Article 4 of the Ordinance on authorizations. According to the Ordinance the license for practice shall not be required for practices involving sealed radioactive sources if the absorbed dose per unit of time at a distance of 0.1 m from any accessible surface of the sealed radioactive source or device accommodating the sealed radioactive source does not exceed 1 μGy per hour under any circumstance. Also the license for practice shall not be required for practices involving depleted uranium shields and ballasts.

5.4. SUMMARY

The existing Act on Radiological and nuclear safety covers the authorization process in the area of use of radiation sources and radioactive waste facility management and authorization of TSO.

The IRRS team concluded that the authorization process established by SORNS is not commensurate with the radiation risk associated with facilities and activities, in accordance with a graded approach. Notification as a document submitted to SORNS by the applicant to notify an intention to carry out a practice, and criteria when notification only is sufficient, are not defined under the existing legal framework. In addition, the Ordinance on authorization prescribing requirements in detail for management of radioactive waste has not been drafted.

Guides for different activities with radiation sources as support to the requirements of the Ordinance on authorizations are not developed. Annexes to the Ordinance provide the format and content of the documents to be submitted by the applicant in support of an application for authorization.

Croatia has established a national register of radiation sources, and it includes radioactive sources of all categories, as well as a register of issued licenses and a dose register that is maintained by SORNS.

Against SORNS' decision by which license was granted or denied, no appeal may be filed, but an administrative dispute may be initiated in accordance with the Act on Administrative Disputes.

Areas of improvements are suggested to ensure completeness and consistency of the existing regulatory framework.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

According to the Act on Radiological and Nuclear Safety, review and assessment is under the responsibility of SORNS and is performed during the authorization process. Information that is reviewed and assessed generally includes the design of the facility, necessary education, health conditions and dose record of workers. Additional information is given in the risk analysis document, which is a part of an application for licence of practice and is the most important document for review and assessment. Content of the risk analysis is given as an attachment to the Ordinance on authorizations and licences for use and movement of ionizing radiation sources. Major chapters are:

- General information on the practice;
- Information on ionizing radiation sources and rooms where they are used (Description of the ionizing radiation source and the device, Dose rate measurement, Classification of areas, Ventilation system, Planned duration of using the ionizing radiation source, Procedure for handling radioactive waste and its disposal and the method of discharge of radioactive substances into the environment);
- Measures for protection of exposed workers and population against ionizing radiation (Protection systems, Administrative protection measures, Use of personal dosimeters and other measurement devices, Personal protective equipment, Programme concerning the testing of ionizing radiation);
- Exposure to ionizing radiation resulting from performing the practice and the disposal of radioactive waste (Description of work procedures, Assessment of irradiation of exposed workers, Assessment of irradiation of a critical group of population resulting from performing the practice involving ionizing radiation sources and the disposal of radioactive waste);
- Emergency procedures;
- Plan for optimizing protection;
- Certifications; and
- Expert opinion of an authorized technical service with proposed measures for risk reduction.

The IRRS team observed that the graded approach in review and assessment is actually not applied. There are some differences between “types of practices” (e.g. import/export, use of ionizing radiation sources, transport etc.) and related documentation that must be submitted to SORNS to be reviewed and assessed, but within the same type of activity, the graded approach is not applied. For all practices (within a particular “type of practice”, e.g. use of ionizing radiation sources) the same documentation must be submitted. Furthermore, all practices involving ionizing radiation sources shall be licenced, except those that are exempted (in this case only licence for use of radioactive sources is required). The IRRS team was informed that it is planned to introduce a system of notification and registration in addition to licencing within the next two years.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

SORNS has not developed written procedures or internal guidelines for the review and assessment of applications for authorization of facilities and activities (including the supporting safety demonstration) (See also Section 10.3 regarding review and assessment of on-site emergency plan and programme). Current practice is based on general procedures defined in the Act on General Administrative Procedure. While reviewing and assessing the documentation, SORNS staff rely on their own knowledge and experience.

The IRRS team was notified that the review and assessment plan that would include prioritization of various submissions does not exist in SORNS. This is because the General Administrative Procedure Act, which has to be applied to all administrative organizations, requires submitted applications to be reviewed and assessed according to the date of their submissions, and any prioritization would represent violation of the provisions of this Act.

In SORNS, the mechanism for monitoring (tracking) the review and assessment process, document control system as well as the quality control of review and assessment processes and documents does not exist.

SORNS has not developed a process to document the review process and justification of regulatory decisions as a feedback from previous review and assessment. There are no arrangements in place to record the results and decisions of reviews and assessment and for ensuring that these are fed back into the regulatory process. Quality control of review and assessment processes and submitted documents are not established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: SORNS has not established a documented process for review and assessment, and written procedures and internal guidance are missing. As a result this can lead to subjectivity in decision-making by the individual staff involved in the review and assessment process.
(1)	**BASIS: GSR Part 1 Requirement 24, para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 Requirement 26 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
R12	**Recommendation: SORNS should establish process and procedures governing the review and assessment activities for all types of facilities and activities under their regulatory control, taking into account graded approach.**

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The IRRS team was informed that, four SORNS employees are involved in authorization and review and assessment process. Some of them did not receive basic training on radiation safety as well as on review and assessment of application for authorization. Specific regulatory tools for review and assessment, such as computer software (e.g. shielding calculation), are not used.

Until now, no committee or working group for review and assessment has been established.

In the case of review and assessment of newly established practices (e.g. cyclotron), for which SORNS staff do not have experience, the IRRS team was informed that SORNS asked for expert support from the IAEA.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The list of documents that must be submitted by an applicant is given in Ordinance on authorizations and licences for use and movement of ionizing radiation sources. The same Ordinance defines the minimum content of the risk analysis document. More detailed instructions related to licencing procedure are not formally issued, but some of the instructions are given on SORNS web page (available only in Croatian). As already mentioned in Section 5, SORNS is legally empowered to require amendments and supplements to the applicant's submitted documentation.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

For any kind of practice involving ionizing radiation sources (except for those which are exempted), risk analysis is one of the documents that must be submitted with the application. As mentioned before, risk analysis, prior to submission to SORNS, must be verified by TSO. It is then reviewed and assessed by SORNS' authorization staff. If needed, SORNS communicates with the applicant, in a way prescribed by General administrative procedure Act. Any decision made during the process of licencing must be given in writing as part of the licence, as prescribed by the same Act.

Formal arrangements for interfacing between review and assessment at authorization and inspections has not been established yet, and authorization staff do not perform verification to confirm validity of the submitted documents during review process before granting a licence. The team observed similar situation for the process of approval of on-site emergency plan and programme (see Section 10.1).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: SORNS does not verify the contents of the documents submitted for review and assessment of an application for authorization by means of inspection.
(1)	**BASIS: GS-G-1.5 para. 3.42 states that** *"A fundamental feature of the process of review and assessment of an application for authorization by the regulatory body is its consideration of the documentation submitted by the applicant. For significant risk sources or unusual or complex practices, the regulatory body should also verify the contents of the documents submitted by means of inspection of the site where the radiation sources are to be installed or used. These inspections will also allow the regulatory body to supplement the information and data needed for review and assessment. Additionally, the regulatory body will be able to extend its practical understanding of the managerial, engineering and operational aspects of the application for authorization and to foster links with specialists of the operating organization."*
S6	**Suggestion: SORNS should consider introducing pre-licensing verification of the contents of the documents submitted for review and assessment of an application for authorization to confirm credibility of submitted documents, where appropriate.**

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The documentary basis on which the review and assessment for radioactive waste management facility are performed is not clearly and sufficiently stated in legislation. Periodic review and assessment is required by national legislation but there are no specific requirements.

The specific requirements for review and assessment for radioactive waste management facility will be covered by issuing the new Ordinance. (See details under Section 5.2.)

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

In addition to generic issues covered in Section 6.1, the way of managing radioactive waste as a product of conducting the activity, in case of radioactive sources, is reviewed and assessed. One of the pre-requisites for granting a licence is that the applicant possesses a valid security plan if the practice involves Category 1, 2 or 3 sources. "Valid" means that the applicant obtained consents issued by SORNS and the Ministry of Interior. In the case of use of "dangerous sources" (definition given in Ordinance OG 123/12), the applicant has to have a valid plan and programme of measures in the event of an emergency, approved by SORNS (see Section 10.1).

6.4. SUMMARY

SORNS has the necessary authority to perform reviews and assessment of applications for licence. Specific training related to review and assessment of staff is however missing. Areas of improvements include the development of clear procedures to govern the review and assessment activities for all types of facilities and activities under their regulatory control based on graded approach.

Technical support organization (TSO) generally have a very important role in the authorization process in Croatia. Many documents submitted to SORNS by the applicant are prepared and verified by TSO, However the technical and other documents submitted by the applicant should be reviewed and accessed by SORNS to determine whether the facility or activity comply with the relevant legal requirement. Obtaining advice and assistance does not relieve SORNS of its assigned responsibilities, which further emphasizes the need for qualified and trained staff for review and assessment in SORNS.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION PROGRAMME

According to the Act on Radiological and Nuclear Safety (OG 141/13) SORNS has the power to conduct inspection activities. The inspection activities are defined by the 2013 Act (Articles 76 to 91).

SORNS carries out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization. Due to the lack of human and financial resources, and also the insufficient experience of inspectors, only a part of the authorized facilities and activities are being covered by inspections. Currently, activities of regulatory inspection not covered are: transport of radioactive sources, import/export of radioactive sources, and research activities, radiotherapy, waste management facilities, and TSOs. On-site emergency arrangements are not covered in the inspection programme (see Section 10.1). Some industrial applications, like radiography and gauges, were recently included in the inspection programme. Moreover, SORNS does not have enough financial resources to fund its inspection programme; therefore inspections are limited mostly to the Zagreb region, unless other practices are inspected upon receipt of information on irregularities or emergency event.

SORNS is conducting planned inspections and reactive inspections in case of emergency or complaints. According to the 2013 Act, the inspector has an obligation to perform inspections without prior announcement, thus excluding announced inspections from the regulatory framework. Unannounced inspections may be conducted as part of a general programme, or with specific aims, but in practice announced inspections are mostly being performed.

There are no provisions that stipulate the frequency of inspections and the areas to be inspected, and inspections are not necessarily commensurate with the radiation risks associated with the facility or activity i.e. is not in accordance with a graded approach.

SORNS' annual inspection programme is drawn up at the end of each year for the year to come. The number of planned inspections as well as the type of the facilities to be inspected depends on the number of employed inspectors, their knowledge and experience. The inspection programme also takes into account information about possible violation of regulations by third parties as well as suspicious facilities identified by other departments, divisions and sectors within SORNS. However SORNS' lack of inner procedures limits the potential cooperation between its different departments, especially between authorization and inspection.

During the procedure of issuance of the approval for performance of operations involving ionizing radiation sources and issuance of the licence for use of ionizing radiation sources for new users, pre-licensing verification are not performed. The IRRS team observed a similar situation regarding pre-approval verifications when approving on-site emergency plan and programme (see Section 10.1). In this case the findings and reports of the TSOs, whose reports and activities were pre-conditions for issuance of all necessary approvals from SORNS, are being relied on.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: SORNS has not established regulatory inspection programme of all facilities and activities. In particular there are no inspections performed at most complex practices, i.e.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	radiotherapy. The inspections of facilities and activities performed by SORNS are not commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.
(1)	**BASIS: GSR Part 1 Requirement 27, states that** "*The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."*
(2)	**BASIS: GSR Part 1 Requirement 29, states that** "*Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
R13	**Recommendation: SORNS should establish inspection programme that commensurate with the radiation risks associated with the facility or activity in accordance with a graded approach that covers all areas relevant to safety and radiation protection and implement this programme.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Although SORNS inspectors carry out announced inspections, the 2013 Act only empowers SORNS inspectors to carry out unannounced inspections.
(1)	**BASIS: GSR Part 1 Requirement 28 states that** "*Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced."*
R14	**Recommendation: The Government should empower SORNS inspectors to carry out announced inspections.**

Suggestion S6 on pre-licencing verification is also covered in Section 6.1.4.

7.1.2. INSPECTION PROCESS AND PRACTICE

SORNS has not established procedures for its inspection activities. Detailed descriptions of some subjects (rights and obligations of inspectors, as well as inspection protocols (check lists), reporting of findings, etc.) are covered in the draft "Manual for conducting inspection supervision". However some areas (e.g. tests and measurements made during inspection) are still not covered by the draft manual. Although the draft has not yet been approved by SORNS' Director General, it is being used in practice for some time already. Also adequate training in following the procedures was not provided to the inspectors concerned.

All inspectors are civil servants therefore have an obligation under the Act on Civil Service to take an examination within six months after receiving a satisfactory assessment on probation. The civil service examination consists of a general and a specific section and must be taken before the Civil Service Commission is organized.

Employees of SORNS are recognized as inspectors when their identity cards and badges are issued by the Director General of SORNS. The official identification card with badge provides official status, identity and powers to the inspector.

According to the 2013 Act while performing an inspection, an inspector has a power to inspect all the working and auxiliary premises and facilities, documents, prescribed registers, equipment, the subjects of work and business under supervision, to take statements from responsible persons and testimonies from witnesses, to perform sampling, and, where necessary, to use services of recognized experts and legal persons. In addition, the inspector is authorized to request and inspect identification documents in order to establish the identity of persons (identification card, passport, etc.).

The set of legal powers given to the inspectors is sufficient for effective supervision of all activities and facilities; however the scope of use of these powers is very limited due to the lack of training and experience of SORNS inspectors.

The SORNS inspection programme incorporates and uses a range of inspection methods listed in IAEA Safety Guide GS-G-1.5 (discussion and interviews, examination of procedures, records and documentation). Due to the lack of appropriate training as well as the lack of procedure for inspections, some important elements of an inspection are not covered, such as measurement, direct observation of working practices and equipment, as well as tests and measurements performed by the inspectors. In addition measurement equipment to be used for inspection is not calibrated.

The inspections are administrative in nature. Inspections are carried out according with check lists, depending on the type of the facility and the radiation source installed. The observations required for the evaluation of the facility are also recorded in the check list.

Results of an inspection are being recorded in an inspection record (resolution) and stored in SORNS' electronic database system. In an inspection record licensees are identified as well as irregularities observed during the inspection. Licensees are obliged to inform the inspector about corrective actions that are taken to eliminate the irregularities within specified timeframes.

On completion of the inspection an exit briefing is being held, with either the operator's representative before whom the inspector had presented his accreditation when arriving to the facility, his substitute (i.e. officially informed to the inspector during the inspection) or the RPO, in this order.

Licensees are allowed to get follow-up information about the case on request. In the process of giving follow-up information, inspector is checking the status of corrective actions or any other data in the inspection record.

There are no procedure for inspection results or other inputs to be used for the development of the inspection process and programme.

The IRRS team members observed an inspection by SORNS inspector at the University Clinical Hospital Sestre Milosrdnice, Department of Nuclear Medicine. The inspection started with an entrance meeting with the Radiation Protection Officer (RPO), who is a medical physicist, and the Chief of the Department who just briefly welcomed the IRRS team members and the inspector. The nuclear medicine department is licensed for use of unsealed sources in diagnostic and therapy, equipped with one (1) CT/SPECT and two (2) Gamma cameras, and with two rooms for patients for cancer treatment. The inspection included the checking of documents required by SORNS (such as certificates of education, dose reports, medical surveillance reports and working procedure) and a visit to the diagnostic and therapeutically part of the department and waste storage. Related documents and records were also checked by the inspector. The inspector then proceeded to the location where the gamma cameras are housed to conduct a visual check of the radiation signs.

In parallel, other IRRS team members observed an inspection by SORNS' inspector at the industrial radiography company. The company is licensed for industrial radiography practice with both X-ray (2) and sealed sources (3). The inspection started with an entrance meeting with the director of the company, who is also an RPO at the company. After a short introduction from the SORNS inspector, the IRRS team

members and representatives of the company, the inspection started. While using the check list, all information on the sources used, staff and their competences, inner procedures, safety and security issues, etc. was collected. After the review of the various documents, the storage where sources are kept was inspected. The second part of inspection covered the checking of serial numbers of X-ray and sealed sources and source movement logs, examining of radiation signs and a quick overview of security measures in place. No direct observation of working practices aimed at gaining a general impression of the operator's capabilities and performance was conducted. No tests or measurements were carried out by the inspector. As a last step, the inspection check list was finalized and main findings of the inspection presented to the director of the company.

The IRRS team members concluded that both inspections concentrated just on administrative matters, and in future should be expanded to include direct observation of the working practices and equipment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: SORNS has not established procedures for its inspection activities. Detailed description of some subjects (rights and obligations of inspectors, as well as inspection protocols (check lists), reporting of findings, etc.) is covered in the draft "Manual for conducting inspection supervision". However some areas (for example tests and measurements made during inspection) are still not covered by the draft manual.
(1)	**BASIS: GSR Part 1 Requirement 32 states that** "*The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.*"
(2)	**BASIS: GS-G-1.5 para. 3.61 states that** "*To ensure that all operators are inspected to a common standard and that the level of safety is consistent, the regulatory body should establish procedures for its inspectors…"*
(3)	**BASIS: GS-G-1.5 para. 3.63 states that** "*The inspection programme of the regulatory body should incorporate and use a variety of methods, as follows:…* *(d) Tests and measurements. The extent to which the regulatory body carries out its own tests and measurements independently of the operator varies greatly between States, depending on such factors as the qualifications of the regulatory inspectors, its regulatory philosophy, and the experience and demonstrated performance of the operators. The regulatory body should not carry out tests and measurements that are the responsibility of the operator. In most instances, tests and measurements carried out by the regulatory body should serve as an independent verification of those tests and measurements performed by the operator."*
R15	**Recommendation: SORNS should review the draft "Manual for conducting inspection supervision" to cover all elements of inspections and approve it.**
S7	**Suggestion: SORNS should review its inspection programme and include tests and measurements as a method of inspection.**

7.1.3. INSPECTORS

There are two out of three positions filled by inspectors in the Department for Inspection. So currently the inspection programme is being implemented by two staff with limited training in inspection and

enforcement, as well in the technical fields where inspections are performed (less than 1 year experience for each inspector). Also some part of the inspection programme is covered under the Head of Service for Inspection and Emergency Preparedness. Because of constant budget cuts, inspectors have only finished "Education and training in basic radiation and safety for radiation workers" in the field of X-ray medical units. The current level of expertise does not enable inspectors to inspect all these authorized practices. In particular, they do not have sufficient knowledge and expertise to inspect TSOs and their work.

The number of qualified and competent staff dedicated to inspection is not sufficient, commensurate with the nature and the number of facilities and activities to be inspected.

The protection of inspectors from the effects of ionizing radiation during inspections is ensured by following precise instructions regarding self-protection. Inspectors use their personal dosimeters (TLD) and are informed on a monthly basis about recorded doses. Inspectors undergo medical examination on an annual basis.

Requirements for knowledge and skills of inspectors are stipulated in the 2013 Act; the tasks of inspectors at SORNS may be performed by persons who have university qualifications in natural or technical sciences. However, the recent Amendments to the 2013 Act on Radiological and Nuclear Safety (OG 39/2015) gives the possibility to persons with other background to be inspectors for radiological and nuclear safety.

Inspectors, as employees of the regulatory body, are civil servants who are obliged to respect the rules of conduct set by the Code of Ethics for Civil Servants. The Code of Ethics contains the ethical principles to be observed by civil servants in the performance of their services.

Recommendation R3 about staffing is given in Section 1.3.

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

At the moment, the Institute Rudjer Boskovic has a licensed facility which was used for the temporary storage of waste. Storage facility was closed a year and half ago by SORNS inspectors who ordered its remediation. The storage facility at the Institute for Medical Research and Occupational Health has never been licensed. Today, this storage facility is closed for the reception of newly generated radioactive waste and disused sources. During 2006, with the assistance of the IAEA and the supervision of the former State Office for Radiation Protection, remediation of the storage facility was carried out. This included the characterization, classification and conditioning of a part of the existing inventory at that time.

SORNS maintains a database where changes in the inventories of both radioactive waste storage facilities are tracked. Operators (the Institute Rudjer Boskovic and the Institute for Medical Research and Occupational Health) are obliged to report every change and submit a complete inventory list to SORNS on a yearly basis.

According to the situation in the area of waste management facilities, inspections are not performed. The facilities are secured and off-site monitoring is regularly ensured by the operators.

SORNS currently does not employ qualified and experienced inspectors in the area of radioactive waste management (See details in Section 7.1.).

7.3. SUMMARY

SORNS carries out limited inspections of facilities and activities. Due to the lack of human and financial resources, and insufficient number of qualified and competent inspectors, the effectiveness of the inspection programme should be strengthened in particular by:

- using a graded approach;

- covering all authorized facilities and activities and regulated areas;
- performing pre-licensing verifications; and
- establishment of procedures for inspection activities.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

In order to deal with non-compliance of licensees, an enforcement policy has been established. Despite that, this policy has not been implemented within the legal framework for responding to non-compliance by licensees with safety requirements or with any conditions specified in their authorizations. The Department of Inspection in SORNS is in charge of the establishment and implementation of the enforcement policy. However due to lack of human resources implementation of this particular task has been postponed.

According to the Act on Radiological and Nuclear Safety, while carrying out an inspection supervision the inspector is being authorized to issue a verbal order to the inspected legal or natural person, temporarily prohibiting the use of working and auxiliary premises or facilities, installations, devices and equipment for performing the activity, as well as prohibiting the work of people until the irregularities will have been rectified. The inspector may also immediately enforce the decision without issuing a special legal act permitting enforcement of the decision in the following cases:

- where there is a hazard or suspicion of a hazard for human health or lives, requiring that a certain safety measure is undertaken immediately, without delay;
- where there is danger or suspicion of danger that evidence could be hidden, replaced or destroyed unless a safety measure is undertaken immediately;
- where the prescribed requirements are not met and can not be met in the course of the normal operation of the facility or activity; or
- where there are gross omissions in the technological process.

Inspectors have the power to make executive decisions on a non-financial obligation, i.e. seal of the premises, installations, devices and other equipment or in another appropriate manner. If the decision cannot be enforced, the inspector has the legal power to enforce fulfilment of the obligations through fines.

If the inspector establishes that violation of regulations represents a misdemeanour, he has an obligation to use the established facts relevant for undertaking measures and file a charge in order to initiate misdemeanour proceedings. Non-compliances, punishable by fines, are listed in The 2013 Act (Articles 92–94).

Besides that, the inspector has a power to temporarily seize objects by means of which a misdemeanour or criminal offence was committed.

Amendments to the Act on Radiological and Nuclear Safety (OG 39/2015) empower the inspector to invoke police escort when required.

SORNS has a legal power to withdraw the approval for performance of operations involving ionizing radiation sources, or/and the licence for use of ionizing radiation sources or the approval for performance of nuclear operations, if it has established that the licence/approval holder or beneficiary does not meet the requirements prescribed by the 2013 Act and its subordinate regulations.

According to the 2013 Act, the licence could be granted or denied by a decision against which no appeal may be filed, but an administrative dispute may be initiated. The procedure for an administrative dispute is prescribed in the Act on Administrative Disputes.

There are no regulations or guides related to enforcement or specific to the enforcement process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There are no detail procedures for determining and exercising enforcement actions. Inspectors have limited training in enforcement procedures and do not have the legal support to carry out enforcement actions.
(1)	**BASIS: GSR Part 1 Requirement 32 states that** "*The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.*"
(2)	**BASIS: GS-G-1.5 para. 3.75 states that** *"Within the legal framework within which it is established, the regulatory body may draft and issue enabling regulations that detail procedures for determining and exercising enforcement actions as well as the rights and obligations of the operator.*
(3)	**BASIS: GS-G-1.5 para. 3.85 states that** *"The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures. The procedures should specify the policy of the regulatory body with regard to the use of regulatory actions and enforcement measures, and the associated delegated authority given to inspectors and to other staff of the regulatory body. … The procedures should cover in detail the decision making approach of the regulatory body in determining the level of action to take and the way in which actions should be taken, including dealing with the failure of the operator to comply with the regulatory enforcement requirements.*
R16	**Recommendation: SORNS should establish detail procedures for determining and exercising enforcement actions. All inspectors and other staff of SORNS should be trained in, and knowledgeable about, the procedures.**
S8	**Suggestion: SORNS should consider providing inspectors with legal support to carry out enforcement actions.**

8.2. ENFORCEMENT IMPLEMENTATIONS

Despite the fact that inspectors have a range of tools for responding to non-compliance of the licensee, the response of SORNS to non-compliance of regulatory requirements or with any conditions specified in the authorization is not in accordance with a graded approach. Taking into consideration the extent of the violations and associated risks, inspector can either prescribe that the licensee eliminates non-compliances within specified time period, or prohibit working with the source of ionizing radiation or work of the exposed worker until the observed non-compliances are eliminated. There are no clear procedures and regulations that detail procedures for determining and exercising enforcement actions.

As a final step of inspection, the report of inspection is drafted. One copy of the report is given to the party that has undergone the supervised inspection. Results of inspections are recorded in the inspection record (resolution) and stored in the electronic database system. In case of non-compliances observed during inspection, terms for corrective actions are given and licensees have an obligation to inform the inspector about corrective actions that are taken to eliminate the non-compliances.

In case of minor non-compliances observed during an inspection, verbal order to the inspected legal or natural person is given together with the corrective actions written in the inspection report. In case of major observed non-compliances, parallel processes of enforcement are started. Firstly, some on-site

enforcement actions (sealing of premises, removing worker from his duty, etc.) are introduced, then, secondly, misdemeanour proceedings during the period of 3 years should be initiated (via the Court). However, there is no clear procedure how these actions should be performed and what evidence should be presented to the prosecutor.

If the access to the object of interest is prohibited by SORNS inspectors, courts have an obligation, upon request, to rule on the court order within one day.

Follow-up inspections currently are not being performed to ensure that corrective actions are implemented, due to lack of human resources.

SORNS has not developed the process and procedures governing the taking of enforcement actions. Therefore inspectors and other staff of SORNS are not properly trained in, and knowledgeable about, the procedures. Moreover, there are no resources inside SORNS for providing legal advice to inspectors. Some official agreements with external legal counsel also do not exist.

In practice only simple means of enforcement i.e. sealing of premises, are currently being used due to lack of training in enforcement procedures and experience of the inspectors.

Education in the field of offence and criminal law is foreseen for inspectors to be able to implement the enforcement policy.

8.3. SUMMARY

In order to deal with non-compliance of authorized parties, an enforcement policy has been established. However implementation of this policy requires:

- process and procedures for determining and exercising enforcement actions;
- inspectors training in enforcement procedures; and
- the availability of legal support.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The current radiation and nuclear safety legislation in Croatia is based on the 2013 Act on Radiological and Nuclear Safety (as amended in 2015), with Regulations issued by the Government and Ordinances issued by SORNS.

Main regulations in the field of radiological and nuclear safety are:

- Regulation on Conditions and Method of Disposal of Radioactive Waste, Spent Sealed Radioactive Sources and Ionizing Radiation Sources which are not Intended for Further Use (Official Gazette 44/08) and
- Regulation on Measures for Protection Against Ionizing Radiation and Interventions in Case of Emergency (Official Gazette 102/12).

Ordinances are issued by SORNS on the basis of the 2013 Act. In the Act on Radiological and Nuclear Safety from 2013 prescribes that new ordinances shall be adopted within two years from the date of the entry into force of this Act. Until the entry into force of the new ordinances, ordinances previously adopted shall remain in force. These ordinances are:

- Ordinance on Performing Nuclear Activities (Official Gazette 74/06);
- Ordinance on Special Requirements Which Expert Organisations Must Fulfil in Order to Perform Certain Activities in the Field Of Nuclear Safety (Official Gazette 74/06);
- Ordinance on the Manner and Procedure for Supervision During Import or Export of Material for Which There is Justified Suspicion of Contamination by Radionuclides or of Containing Radioactive Sources (Official Gazette 114/07);
- Ordinance on Radioactive Decontamination, Radioactive Source Management and Carrying Out of All Other Necessary Measures in Order to Reduce Impacts on Human Health and Environment or to Avoid Additional Risks, Dangers or Damages (Official Gazette 53/08);
- Ordinance on Conditions for Nuclear Safety and Protection With Regard to the Siting, Design, Construction, Use and Decommissioning of a Facility in Which a Nuclear Activity is Performed (Official Gazette 71 /08) and
- Ordinance on the Requirements for the Design, Construction and Removal of Structures Accommodating Sources of Ionizing Radiation or in Which Practices Involving Sources of Ionizing Radiation Take Place (Official Gazette 99/08).

Ordinances issued on the basis of the Act on Radiological and Nuclear Safety from 2010 are:

- Ordinance on the Official Identity Card and Badge of the Radiological and Nuclear Safety Inspector (Official Gazette 28/11);
- Ordinance on Required Professional Training for Operating Sources of Ionizing Radiation and for the Application of Measures for Protection Against Ionizing Radiation (Official Gazette 63/11);
- Ordinance on Giving Permissions to the Expert Technical Services to Perform Expert Tasks Related to the Ionizing Radiation (Official Gazette 72/11);
- Ordinance on Physical Protection of Radioactive Materials, Nuclear Materials and Nuclear Objects (Official Gazette 38/12);

- Ordinance on the Personal Dosimetry on the Examination of Ionizing Radiation Sources and Working Conditions and on the Reports and Inquest Registers (Official Gazette 41/12, amended 89/13);
- Ordinance on Permissions and Allowances for the Application and Transport of the Ionizing Radiation Sources (Official Gazette 71/12, amended 89/13);
- Ordinance on the Scope and Content of the Plan and Programme of Measures in the Event of an Emergency and of Informing the Public and Competent Bodies (Official Gazette 123/12);
- Ordinance on the Supervision and Control of Transboundary Shipments of Radioactive Waste and Spent Fuel (Official Gazette 11/13);
- Ordinance on Conditions and Measures for the Protection Against the Ionizing Radiation in Performing the Activities with Radioactive Sources (Official Gazette 41/13);
- Ordinance on the Conditions and Measures of Ionizing Radiation Protection for Performing Operations Involving Electrical Devices Generating Ionizing Radiation (Official Gazette 41/13);
- Ordinance on the Conditions and Procedure for Issuing and Withdrawing the Approval for Packaging Used for Transport of Radioactive and Nuclear Materials (Official Gazette 42/13) – issued on the basis of the Dangerous Goods Transport Act;
- Ordinance on Exposure Limits (Official Gazette 59/13);
- Ordinance on Health Conditions of the Exposed Workers and Persons Being Educated to Work with the Ionizing Radiation Sources (Official Gazette 80/13);
- Ordinance on the Conditions for Application of Ionizing Radiation Sources in Medicine and Dentistry (Official Gazette 89/13);
- Ordinance on the Monitoring of the Radioactivity in the Environment (Official Gazette 121/13);
- Strategy for the management of radioactive waste, disused sources and spent nuclear fuel (Official Gazette 125/14) – issued on the basis of the Act on Radiological and Nuclear Safety from 2013.

Croatia as a Member State of the European Union directly adopts EU regulations and transposes EU Directives into Croatian national legislation.

SORNS' formal process for issuing new regulatory requirements, or changing existing ones, is prescribed by Act on State Administration System (OG 150/11). According to the Code of Practice on Consultation with the Interested Public in Procedures of Adopting Laws, other Regulations and Acts (OG 140/09), public (expert or other) is actively involved in the process of proposing or changing of any kind of legislation (act, regulation, ordinance). For that purpose, all drafts and proposals are published on SORNS website, with the announcement of the period of time for interested public to provide their opinions or comments.

The fact that SORNS is empowered to write ordinances does not diminish the need for SORNS to prepare and issue guides. Although these are legally non-binding, guides provide detail guidance to the licensees on how to comply with the safety requirement. SORNS should have a detailed annual work plan to develop/revise regulations/guides.

Although most of the regulations of SORNS are established in reference to IAEA safety standards, there is no mechanism to ensure that the regulations are fully harmonized and updated with the requirements of IAEA safety standards. This may result in using out-of-date safety standards.

The IRRS team has observed that some of the requirements from the existing regulatory framework are not fully implemented in practice. (e.g. Section 10 and 11.1)

No formal process has been established to identify the impact of changes to regulatory requirements, the identification of gaps with existing practices and transitional plans for implementation.

The current regulations and ordinances relevant to emergency preparedness and response do not comprehensively cover all the necessary functions to be performed by operators in an emergency response and the infrastructure to be put in place by them as required by IAEA Safety Standards (GS-R-2). This is addressed in Sections 10.2 and 10.3.

The regulatory framework defining medical exposure, especially the ordinance OG 89/13, does not cover the full scope of the requirements of GSR Part 3, especially regarding justification, optimization, and unintended exposure. This is addressed in Section 11.1.

With respect to control of occupationally exposed workers, SORNS should review and revise Ordinance OG121/13 in relation to cosmic radiation and exposure to radon. This is addressed in Section 11.2.

With respect to control of radioactive discharges, Regulation 44/08 'on the conditions and method of disposal of radioactive waste, spent sealed radioactive sources and ionizing radiation sources which are not intended for further use' does not address limits for liquid and gaseous radioactive discharges in accordance with IAEA standards. This is addressed in Section 11, Section 11.3.1.

With respect to environmental monitoring for public radiation protection, Ordinance 121/13 'on the environmental monitoring of radioactivity' needs to be adapted to reflect the approach described in RS-G-1.8. This is addressed in Section 11.3.2.

With respect to remediation of areas contaminated with residual radioactive material, Ordinance 53/08 'on the ways of removal of radioactive contamination, disposal of radioactive sources, or undertaking other indispensable measures to reduce damage to people and the environment or eliminate further threats' does not address remediation of areas contaminated with residual radioactive material. This is addressed in Section 11.3.3.

RECOMMENDATIONS, **SUGGESTIONS AND GOOD PRACTICES**	
	Observation: SORNS does not prepare and issue guides, as a part of a comprehensive regulatory framework, to provide guidance on how to comply with the safety requirement.
(1)	**BASIS: GSR Part 1 Requirement 32 states that** "*The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.*"
S9	**Suggestion: SORNS should consider developing guides to help users striving to achieve the high levels of safety.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There is no formalized process in place for the review of regulations, which ensures that a systematically periodical review is done.
(1)	**BASIS: GSR Part 1 Requirement 33 states that** "*Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.*"

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S10	**Suggestion: SORNS should establish within its regulatory framework processes and procedures for reviewing and revising regulations, taken into account internationally agreed standards and the feedback of relevant experience.**

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The Strategy was established and promulgated by the Parliament. The National Programme for Implementation of the Strategy is prepared but not approved by the Government of the Republic of Croatia. The legislative framework in the Republic of Croatia, in the section pertaining to the management of radioactive waste and spent nuclear fuel, requires supplementation and alignment with the appropriate internationally recognised criteria and standards (See details under Section 9.1.).

Radioactive waste categorization is based on the IAEA recommendation given in Classification of Radioactive Waste, IAEA Safety Guide No. 111-G-1.1, 1994 and is covered under Article 13 and 14 of the Regulation OG 44/08. Revision of the above mentioned Regulation is under development and a new radioactive waste categorization is supposed to be developed in accordance with Classification of Radioactive Waste, IAEA General Safety Guide No. GSG-1, 2009.

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

SORNS has developed several regulations applicable to radiation sources, which specify principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based.

Existing regulations do not fully reflect the latest IAEA safety requirements. The system of regulations in the country also does not fully reflect a graded approach. The regulations covers the main provisions for the safety of radiation sources: requirements for medical, occupational and public exposure control as well as some emergency procedures for the licensee, based on risk analysis document, as well as some details for licensing processes.

An assessment system for ensuring that all regulations are in place is not established. SORNS has not identified which requirements in the regulations and which standards are applicable to each type of facility or activity.

SORNS has established requirements for radiation protection that do not fully comply with GSR Part 3. Elements related to the qualified expert for radiation protection and medical physics expert are missing. There are no references for the types of exposure situation regarding planned, existing and emergency exposure situations. It is not required from the user to ensure that protection and safety are effectively integrated into an overall management system of the facilities and activities for which they are responsible. The graded approach for the application of the requirements in planned exposure situations is not commensurate with the characteristics of the practice or the source within a practice, and with the magnitude and likelihood of the exposures. Investigations and feedback of information on operating experience, for conducting formal investigations of abnormal conditions arising in the operation of facilities concerning disseminated information on lessons learned for protection and safety, are not adopted in any regulation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The existing regulations and ordinances for radiation safety are not fully in line with the IAEA GSR Part 3.
(1)	**BASIS: GSR Part 1 Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
S11	**Suggestion: SORNS should consider reviewing its ordinances for compliance with GSR Part 3.**

9.4. SUMMARY

In Croatia the legal basis for developing regulations for nuclear and radiation safety is clearly defined. There is a general governmental process for the approval, issue and promotion of regulations, including those under the responsibility of SORNS.

Although most of the regulations of SORNS are established in reference to IAEA safety standards, there is no mechanism to ensure that the regulations are fully harmonized with the requirements in IAEA safety standards. This may result in using out-of-date safety standards, such as in the case for the requirements in GSR Part 3.

A graded approach commensurate with the radiation risks associated with facilities and activities in Croatia appears not to have been applied in the content of the regulations.

The IRRS team observed that some of the requirements from the existing regulatory framework are not fully implemented in a practice.

No formal process has been established to identify the impact of changes to regulatory requirements or to the identification of gaps with existing practices. The period of consultation is however formalized.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Basic responsibilities

Regulatory framework in the area of emergency preparedness and response (EPR) is set in the 2013 Act 141/13(39/15)[1] and several subordinate regulations and ordinances, primarily Regulation 102/12[2] and Ordinance 123/12[3]. The 2013 Act 141/13(39/15) establishes SORNS as a competent authority pertaining nuclear and radiological safety (Art. 7) and clearly includes EPR. SORNS has been given the authority to approve and supervise operator's emergency arrangements and to carry out inspections over implementation of the 2013 Act and subordinate regulations and ordinances in this regard. However, the current regulations and ordinances do not comprehensively cover all the necessary functions to be performed by operators in an emergency response and the infrastructure to be put in place by them as required by IAEA Safety Standards (see Sections 10.2 and 10.3). Moreover, SORNS does not perform inspections over operator's emergency arrangements and does not evaluate any of their exercises (see Section 10.3).

Act 141/13(39/15) requires that operators put in place emergency plan and programme which are subject to approval by SORNS consistently with GS-R-2 and GSR Part 1. However, subordinate Ordinance 123/12 requires on-site emergency plan and programme to be developed only by operators using dangerous sources (see below Assessment of threats).

The 2013 Act 141/13(39/15) gives SORNS also other responsibilities in both emergency preparedness and emergency response and assigns it as a competent authority regarding early notification in a case of a nuclear or radiological emergency as described in Section 10.4. In addition, the Regulation 102/12, Art. 35, gives SORNS a responsibility to approve emergency plan and programme of scrap metal operators; however, this has not been implemented yet. In fulfilment of its functions in EPR, SORNS is entitled (Article 40 of Regulation 102/12) to obtain assistance from authorized Technical Support Organizations (TSOs) and/or authorized experts for nuclear safety.

Regulation 102/12 describes who the participants in the emergency response systems are in Croatia. In addition to operators, state administrative bodies (including SORNS, Protection and Rescue Directorate, the Ministry of Health, the Ministry of Agriculture etc.), local and regional self-governments, authorized TSOs, firefighting services, etc. are recognized off-site emergency response organizations.

Assessment of threats

Act 141/13(39/15) requires that the operators ensure adoption and regular updating of a risk analysis. The content of the risk analysis is part of Ordinance 71/12(89/13)[4] and it includes consideration of potential emergencies and associated consequences and risks. Based on Ordinance 123/12, operator's emergency plan and programme need to identify all potential emergencies irrespective of the cause and provide assessment of the consequences taking account of this risk analysis which is consistent with GS-R-2, GS-G-2.1.

[1] Act on Radiological and Nuclear Safety (OG 141/13, 39/15)
[2] Regulation on Measures for Protection Against Ionizing Radiation and Interventions in Case of Emergency (OG 102/12)
[3] Ordinance on the Scope and Content of the Plan and Programme of Measures in the Event of an Emergency and of Informing the Public and Competent Bodies (OG 123/12)
[4] Ordinance on Authorization and licenses for use and movement of ionizing radiation sources (OG 71/12, 89/13)

Regulation 102/12 describes threat categories to be associated with facilities, activities and sources (within Croatian borders and those beyond) that may give rise to emergencies warranting emergency response actions on the Croatian territory, generally in consistency with GS-R-2, GS-G-2.1. This is a generic description of the categories for which emergency plans and programmes need to be prepared using a graded approach. However, the team was informed that SORNS has not been using them in practice whatsoever and noted that postulating emergencies within some operator's emergency plan and programme is not linked to defined threat categories. Facilities, activities and sources present in Croatia are not categorized based on the hazards associated with them in line with the Regulation 102/12 and thus, not all operators of facilities and activities within threat category III and IV are required to prepare on-site emergency plan and programme on a basis of a graded approach. Namely, the emergency plan and programme is a prerequisite to the authorization process and subject to approval by SORNS only in relation to dangerous sources (defined in Regulation 123/12; currently 51 operators of dangerous sources exist in SORNS records of which 31 operators have approved emergency plan and programme). For other facilities and activities involving ionizing radiation sources other than dangerous sources, such as accelerators in radiotherapy (currently, 5 operators at 8 locations use 16 accelerators in radiotherapy), emergency plan and programme are not prerequisite to the authorization process. Based on Art. 3 of Regulation 123/12, SORNS may decide to request for development of emergency plan and programme on the basis of the risk analysis submitted during the authorization process. However, the IRRS team was informed that no facility or activity using ionizing radiation sources other than dangerous sources has been requested to develop on-site emergency arrangements so far.

SORNS has identified the category of radioactive sources (in line with GSR Part 3). This categorization has also been used to determine what radioactive sources are to be considered as dangerous sources. The IRRS team was informed that SORNS has also shared this information with local 112 services in accordance with Art. 39 of Regulation 102/12.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: SORNS has the responsibility to regulate on-site emergency arrangements of operators based on Act 141/13(39/15). The current legislation in EPR do not comprehensively cover all the necessary functions to be performed by operators in an emergency response and the infrastructure to be put in place by them as required in IAEA Safety Standards (GS-R-2). SORNS does not apply a graded approach in regulating on-site emergency arrangements, does not perform inspections in EPR and does not evaluate any of their exercises. This is not consistent with IAEA Safety Standards (GS-R-2, GS-G-2.1).
(1)	**BASIS: GS-R-2 para. 3.2 states that** *"The arrangements for emergency response actions both within and outside facilities, if applicable, or elsewhere under the control of the operator, are dealt with through the regulatory process."* **GS-R-2 para. 3.8 states that** "*The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. […]"* *In addition, the following paragraphs provide basis for this recommendation:* ***GS-R-2, paras. 3.15, 4.57, 4.58, 4.61, 4.62, 4.78, 4.69, 4.70, 4.60, 4.65, 4.97, 5.3, 5.7, 5.10, 5.14, 5.25, 5.31, 5.33.***
R17	**Recommendation: SORNS should revise and strengthen its regulatory framework in EPR consistently with IAEA Safety Standards to also include inspection, enforcement**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	and evaluation of some of operator's exercises and should implement a graded approach.

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Identifying, notifying and activating

Regulation 102/12 requires that operators in an emergency inform promptly SORNS through 112 system which acts as an off-site notification point consistently with GS-R-2, GS-G-2.1. The requirements for activation of off-site response and process for requesting support by operators from off-site emergency services through local 112 systems are in place consistently with GS-R-2, GS-G-2.1. However, SORNS has neither set response time objectives for this notification and activation of emergency response nor it has tested in an exercise. In addition, Regulation 102/12 does not require operators to develop observable conditions, emergency action levels etc. (as a basis for emergency classification) for them to identify emergency conditions and to activate an adequate level of emergency response promptly. This is not consistent with GS-R-2, GS-G-2.1 and GS-G-2.

Ordinance 123/12 addresses the information that operators need to submit to SORNS in an emergency as an initial notification and thereafter, regularly. Procedures for doing so have been provided in the several on-site emergency plans examined by the team.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The current legislation in EPR do not require operators to identify promptly conditions indicative for an emergency situation, to notify the emergency and to activate an emergency response within some reasonable response time objectives as required in IAEA Safety Standards (GS-R-2 and GS-G-2.1).
(1)	**BASIS: GS-R-2 para. 3.8 states that** "*The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. […]"*
	GS-R-2 para. 4.19. states that *"The operator of a facility or practice in threat category I, II, III or IV shall make arrangements for the prompt identification of an actual or potential nuclear or radiological emergency, and determination of the appropriate level of response. This shall include a system for classifying all potential nuclear and radiological emergencies […]"*
R18	**Recommendation: SORNS should require that operators develop and implement a system for classifying all potential nuclear or radiological emergencies and for activation of an adequate level of emergency response consistently with IAEA Safety Standards.**
S12	**Suggestion: SORNS should consider setting response time objectives for notification of an emergency and for activation of an emergency response.**

Establishing emergency management and operations

Regulation 102/12 describes the national emergency organization for managing emergencies in threat categories I-V in a general matter, at a level of response organizations. In addition, Government assigned SORNS a role to manage and implement protective actions on-site for facilities and activities in threat categories III and IV under the responsibility of an operator. This is not consistent with SORNS responsibilities and operator's responsibilities set forth in the 2013 Act 141/13(39/15) and it is not in line with GS-R-2, GSR Part 1, GS-G-2.1.

As a result, current regulations and ordinances in EPR do not require operators to set their emergency organization (for the management of on-site emergency response, for transitioning from normal operations to emergency operation command and control and for coordination with off-site emergency response) and to develop necessary arrangements to take mitigation actions and urgent protective actions on-site. This is not consistent with GS-R-2.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Regulation 102/12 assigns SORNS a responsibility to manage the on-site emergency response, to implement urgent protective actions at the site of relevant facilities and activities under the responsibility of an operator and in this regard, to provide public information as a single source. This is not consistent with SORNS responsibilities and operator's responsibilities set forth in the 2013 Act 141/13(39/15) and with IAEA Safety Standards (GS-R-2).
(1)	**BASIS: GS-R-2 para. 4.84 states that** *"The operator, the response organizations, other States and the IAEA shall make arrangements for co-coordinating the provision of information to the public and to the news and information media in the event of a nuclear or radiological emergency…"*
(2)	**BASIS: GS-R-2 para. 3.10 states that** *"In planning for, and in the event of [a nuclear or radiological emergency], the regulatory body shall act as an adviser to the government and [response organizations] in respect of nuclear safety and radiation protection."*
(3)	**BASIS: GS-R-2 para. 4.10 states that** *"Arrangements shall be made for the implementation of a command and control system for the response to a nuclear or radiological emergency. […]"*
(4)	**BASIS: GS-R-2 para. 5.23 states that** *"On-site emergency plans shall be implemented by [the operators]."*
	In addition, the following paragraphs provide basis for this recommendation: ***GS-R-2, paras. 4.19, 4.3, 4.51***
R19	**Recommendation: The Government should review and revise the responsibility of SORNS to manage the on-site emergency response, to implement urgent protective actions on-site in relation to facilities and activities under the responsibility of an operator and, in this regard, to provide public information as a single source.**
R20	**Recommendation: SORNS shall require operators to implement clear command and control system to manage effectively the on-site emergency response.**

Taking mitigation actions

Regulation 102/12 does not explicitly give responsibility and authority to operators to prepare for and to take mitigation actions in an emergency involving the facility or activity under their responsibility. It also does not address the provision of off-site services to operators of facilities and activities in category III and IV which is not consistent with GS-R-2. However, the Ordinance 123/12 requires operators to address emergency response and immediate activities undertaken to mitigate the adverse consequences on the site, although in a very generic manner. The IRRS team examined several emergency plans and noted that the information on assessed types of necessary support from off-site services (firefighters, medical service etc.) is indicated in the initial notification form submitted to the local 112 service. This notification is thereafter received by SORNS duty officer who may delegate and activate additional support such as authorized TSOs. The team noted that off-site emergency services are available to support on-site response consistently with GS-R-2. However, such off-site support to operators has not been formally arranged.

SORNS has not been requiring and assessing the coordination and integration of on-site emergency arrangements with those of other off-site emergency response organizations (such as police, firefighting services, medical services, protection and rescue organization etc.). However, SORNS requires that operators who deal with dangerous sources to inform the local and regional self-governments on the emergency plan and programme. The IRRS team witnessed the provision of this information on several operators' websites.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Off-site emergency services are available to support the on-site emergency response as required in IAEA Safety Standards (GS-R-2). However, this off-site support has not been formally arranged among operators and support providers to ensure its availability and reliability when needed.
(1)	**BASIS: GS-R-2 para. 5.10 states that** *"Arrangements for the co-ordination of emergency response and protocols for operational interfaces between operators and local, regional and national governments shall be developed, as applicable."*
S13	**Suggestion: SORNS should consider requesting that operators establish formal arrangements or protocols with off-site emergency services providing the operator with an assistance and support during the on-site emergency response.**

Taking urgent protective action

Regulation 102/12 does not explicitly give responsibility and authority to operators to prepare for and to take urgent protective actions and other response actions on-site in an emergency involving the facility or activity under their responsibility as this has been a responsibility to SORNS as discussed above.

Regulation 102/12 requires SORNS' Director General to designate areas/zones for implementing urgent protective actions and threat perimeters based on the risk assessment of Croatia for facilities in threat categories I and II. In this regard, the Slovenian authority has initiated a dialog with SORNS to harmonize the emergency response strategies on both sides of the border in relation to nuclear emergency at Krško NPP. While progress has been made in strengthening the cooperation with Slovenia, no final decision has been reached so far for establishing common emergency planning zones in consideration of GS-R-2 and GS-G-2.1.

SORNS has issued an ordinance (Ordinance 59/13[5]) in which it prescribes the intervention levels and generic action levels for implementing specific urgent protective actions consistently with GS-R-2. However, these levels have been superseded in 2011 when GSG-2 and GSR Part 3 were published. The current regulations and ordinances do not require development of operational intervention levels as required in GS-R-2, GS-G-2.1 and GSG-2. The IRRS team noted that some of the examined emergency plans contain practice-specific operational intervention levels.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Based on Regulation 102/12, SORNS has a responsibility for defining the emergency planning zones in relation to Krsko NPP in Slovenia and has initiated dialog with Slovenia to harmonize response strategies on both sides of the border. The intervention levels at which protective actions need to be taken in an emergency, which are part of Ordinance 59/13, are not in line with the latest IAEA Safety Standards (GSG-2, GSR Part 3).
(1)	**BASIS: GS-R-2 para. 4.50 states that** *"The jurisdictions within the precautionary action zone and/or the urgent protective action planning zone shall make arrangements to take appropriate urgent action promptly upon the notification of a nuclear or radiological emergency […]."*
(2)	**BASIS: GSG-2 para. 3.6 states that** *"The generic criteria replace the system of generic intervention levels (GILs) and generic action levels (GALs) that have been described in previous standards…."*
S14	**Suggestion: SORNS should consider continuing its efforts to coordinate and harmonize emergency planning zones with their Slovenian counterparts in relation to Krsko NPP in line with relevant IAEA Safety Standards.**
S15	**Suggestion: SORNS should consider updating the intervention levels and generic action levels for taking protective actions set forth in Ordinance 59/13 taking account of the latest IAEA Safety Standards.**

Providing information and issuing instructions

Regulation 102/12 sets out that the provision of information and issuing instructions to potentially affected population and educating them on hazards present, radiation induced effects, actions planned to alert, protect and assist them in an emergency is a duty of all participants in the emergency response system and thus, to operators and SORNS too, which is consistent with GS-R-2. Such information is placed on websites of operators consistently with approved emergency plan and programme.

Regulation 102/12 requires that SORNS provides information to the public in relation to emergency associated with facilities and activities in threat category III and IV under the responsibility of an operator. In line with this regulation, Ordinance 123/12 does not require that operator's emergency plan and programme contain arrangements for public information during an emergency. This is not in accordance with GS-R-2 which requires that operators and response organizations make arrangements for coordinating the provision of useful, timely, consistent and coordinated information to the public in an emergency.

[5] Ordinance on exposure limits (OG 59/13)

Assessing the initial phase

Current regulations in EPR do not require operators to put in place arrangements to assess the emergency situation on-site and its impacts off-site during an emergency as required in GS-R-2. However, Ordinance 123/12 requires operators to provide the expert basis for assessment as part of their emergency plan and programme. SORNS neither has issued a regulatory guide to operators on what they are expected to cover in this part nor does it have a procedure to guide its review and assessment of this part of emergency plan and programme. The IRRS team noted limited coverage of this topic in the examined emergency plans and programmes.

Managing the medical response

Current regulations in EPR do not require operators to put in place arrangements for medical response on-site in an emergency as required in GS-R-2. However, medical services are available to operators as discussed above.

Protecting emergency workers

The responsibilities in relation to protection of emergency workers on-site (coming from operator's employees and from off-site emergency services) and the arrangements necessary to be put in place by operators to protect emergency workers on-site are not established in the current acts, regulations and ordinances in EPR which is not consistent with GS-R-2 and GSR Part 3 (see also Section 11 on Occupational radiation protection).

Act 141/13(39/15), Regulation 102/12, Ordinance 59/13 provide some requirements regarding those persons/teams responding to an emergency (such as limitations of doses to be incurred when taking specific tasks, need for training and predetermination of these persons/teams, need for them to be prepared and informed on risks). Some emergency plans and programme that have been examined cover aspects of accepting and protecting emergency workers on-site including those from off-site services although this is not required or evaluated systematically by SORNS.

Current acts, regulations and ordinances in EPR, do not define who is to be regarded as an emergency worker. Emergency workers need to be defined consistently with GSR Part 3 and designated at preparedness stage (see Section 11 on Occupational radiation protection).

Other activities in emergency preparedness

Act 141/13(39/15) gives the responsibility to operators to handle the remediation at their own expenses in relation to sources under their responsibilities. However, current acts, regulation and ordinances in EPR do not require operators to put in place arrangements for carrying out recovery on-site as required in GS-R-2. This may have been result due to SORNS having responsibility to manage the on-site response as discussed above.

Regulation 102/12 requires SORNS to develop proposals on temporary and permanent relocation, on agricultural countermeasures and on control of transboundary movement of people and goods to relevant competent authorities at national level. SORNS sets out intervention levels for these actions in Ordinance 59/13 which need to be updated in the light of the latest IAEA Safety Standards (GSR Part 3, GSG-2).

Current acts, regulation and ordinances in EPR do not set requirements on either operators or SORNS regarding measures to mitigate non-radiological consequences although they have responsibilities in public information which is one aspect of contributing to minimizing these consequences.

Ordinance 123/12 requires operator to compile a report on an analysis of the emergency and emergency response and on corrective actions identified and to report to SORNS. This is consistent with GS-R-2. Up to now, SORNS has not got any such report from either of its operators.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Authority

The assignment of authorities regarding relevant functions in EPR is discussed in 10.1 and 10.2.

Organization

The relevant aspect of organization is discussed in 10.2. Act 141/13(39/15) requires sufficiency of suitably qualified staff to be ensured by operators. However, the current acts, regulations and ordinances in EPR do not set staffing requirements for the operators regarding EPR. This is not consistent with GS-R-2.

Coordination of emergency response

The relevant aspect of coordination of EPR of operators with off-site emergency services is discussed in 10.2.

Plans and procedures

Act 141/13(39/15) requires that all operators put in place emergency plan and programme which are subject to approval by SORNS, which is consistent with GS-R-2 and GSR Part 1. Regulation 123/12 provides what the contents and format of the operator's emergency plan and programme are, but it covers EPR aspects only in general terms.

The IRRS team examined several emergency plans and programmes that were approved by SORNS and noted that some of them address the regulatory requirements to a limited extent while some EPR aspects that are not part of current legislation and regulations had been found to be elaborated in them. Thus, the IRRS team noted that preparation and assessment of the operator's emergency plan and programmes is not done comprehensively and systematically.

There is not a regulatory guide to help operators in the development of the emergency plan and programme. In addition, SORNS has not developed internal process, including checklists, for review, assessment and approval of the operator's emergency plan and programme. This is done by SORNS staff on the basis of reviewer's expertise and judgement on the submitted documentation.

SORNS does not carry out inspection as means to verify the adequacy of elaborated emergency arrangements prior to approval. SORNS does not perform inspection over operator's emergency arrangements and does not evaluate any of exercises carried out by operators. This is not consistent with GS-R-2.

Logistical support and facilities

The current acts, regulations and ordinances in EPR do not set requirements on the operators regarding logistical support and facilities needed to support the emergency response. This is not consistent with GS-R-2.

Training, drills and exercises

Act 131/14 requires persons handling ionizing radiation sources to have adequate qualification and (re)training. Ordinance 123/12 requires operator's emergency plan and programme to contain information on the manner and deadlines for implementation of training and drills. However, in an absence of a regulatory guide, SORNS does not require, review and assess the training and exercise programmes as part of operator's emergency plan and programme.

Quality assurance programme

Act 141/13 requires that the operators ensure quality assurance programme. In addition, Ordinance 123/13 requires operator's emergency plan and programme to contain information on the manner and deadlines

for updating data and information and other preparedness activities as well as on period review of the emergency plan and programme through conduct and evaluation of drills. While this is in part consistent with GS-R-2, still the current acts, regulations and ordinances in EPR do not comprehensively require for quality assurance programme to be maintained by operators within their management system for ensuring availability and reliability of all the supplies, equipment, communication system, facilities etc. and for ensuring all relevant documentation (plans, procedures, instruction, checklist, lists of contact details etc.) are up to date.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The operator's emergency plans and procedures are not developed and evaluated in a comprehensive manner taking into account relevant acts, regulations and ordinances in EPR and the hazards associated with their facilities and activities.
(1)	**BASIS: GS-R-2 para. 3.2 states that** *"The arrangements for emergency response actions both within and outside facilities, if applicable, or elsewhere under the control of the operator, are dealt with through the regulatory process."*
	GS-R-2 para. 3.9 states that *"In fulfilling its statutory obligations, the regulatory body… shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;… shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified):… the requirements for incident reporting;…and emergency preparedness arrangements."*
R21	**Recommendation: SORNS should develop a regulatory guide to facilitate systematic development of on-site emergency arrangements by operators and an internal process to facilitate its systematic review and assessment of the operator's emergency plan and programme.**

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

The primary roles of SORNS in a nuclear or radiological emergency response are set forth in the 2013 Act 141/13(39/15), Act on protection and rescue 174/04(79/07, 38/09, 127/10), Early Notification Convention, Assistance Convention, Regulation 102/12, and the Protection and Rescue Plan (96/10) as following: gathering relevant information and analysis; assessment of the consequences and provision of advice; provision of public information; notification of other organizations and international community (IAEA, EC, neighbouring States) as a competent authority in the area and preparation of proposals to the Government for requests of international assistance. In addition, SORNS has the roles to organize and supervise the environmental monitoring in an emergency and to coordinate and direct the control of efficiency of decontamination measures carried out by authorized TSOs.

The current legislation requires SORNS to prepare Standard Operating Procedures (SOPs) in consideration of these roles. SORNS has developed draft SOPs only in consideration of its primary roles but the IRRS team noted no consideration of SORNS regarding additional roles. The IRRS team was informed that the draft SOPs had been tested in a joint exercise with Slovenia in November 2014 when they proved to be inadequate and thus, the adoption of SOPs was postponed. The IRRS team noted additional procedures available in SORNS for assessment of consequences in a nuclear or radiological emergency (e.g. for evaluation of consequences in the case of accident in Krsko NPP, procedure for use of

RODOS) and for use of several tools (e.g. a software operationalizing IAEA TECDOC-955) for that purpose. The IRRS team was informed that these procedures were in use by the State Offices on radiological safety and on nuclear safety before they merged in SORNS. However, neither of these procedures or tools are in use anymore nor SORNS has a plan to revise them taking into account new organization and the latest development in the area.

Current organization of SORNS for managing its emergency response relies on duty offices (in total, 4 inspectors being on duty 24/7 in weekly shifts) and the EPR staff (one senior expert in EPR and one managerial level staff). The working instruction for the duty officers is very general and primarily focuses on activation of the response of SORNS as well as of other supporting organizations (primarily, authorized TSOs) in case of any type of nuclear or radiological emergency. The duty officer acts in response only in the case of radiological emergencies using SORNS equipment and authorized TSOs' advices as necessary. The remaining EPR staff takes over other responsibilities such as: making assessments (using RODOS, IAEA publications and advices from authorized TSOs or external experts in nuclear safety, data obtained from the Early Warning System) on the situation based on the information received by the duty officer, by operators or other organizations; preparation and submission of notifications to IAEA, EU and other States as necessary; and preparation of press releases including rating the event on INES.

No emergency organization (except the duty officers) is developed by SORNS to manage its roles in response that is appropriately staffed at all necessary positions. SORNS did not put in place its emergency plan and procedures. SORNS does not have training, exercise and quality assurance programme in EPR. This is not consistent with GS-R-2. However, SORNS has a dedicated emergency Centre that is well equipped with necessary equipment (computers, printers, tools such as RODOS, maps), communication systems (land, mobile, radio, facsimile), documentation, supplies etc.

The IRRS team noted that SORNS relies, to a great extent, on support from authorized TSOs and external experts on nuclear safety in an emergency; however, no formal arrangements or protocols are made by SORNS to ensure that they can get the support when needed.

The IRRS team noted the roles of SORNS to organize and supervise environmental monitoring in an emergency and to coordinate and direct the control of efficiency of decontamination measures carried out by authorized TSOs in an emergency which go beyond those contained in GS-R-2 and GSR Part 1. These roles may result in a conflict of interest as the authorized TSOs act at the same time as support to SORNS and/or to an operator and as a national response organization as well while diminishing the roles of operators and the roles other organizations may have in this regard. Based on the IAEA safety standards, all the roles in emergency response (including monitoring and decontamination) need to be assigned clearly and unambiguously among all the relevant response organizations in the legislation and regulations and response organizations need to make arrangements at the preparedness stage for fulfilment of their roles.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The 2013 Act 141/13(39/15) and Regulation 102/12 assign the roles of SORNS in emergency response which include assessment of the situation, provision of technical advice and public information, early notification, organization of environmental monitoring and efficiency control of decontamination. SORNS does not have its emergency plan and procedures necessary to fulfil these roles effectively in an emergency response as required in IAEA Safety Standards (GS-R-2, GS-G-2.1). Currently, SORNS relies on support from authorized TSOs and external experts in nuclear safety without any formal arrangements or protocols being made to ensure availability and reliability of this support

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	when needed.
(1)	**BASIS: GS-R-2 para. 5.14 states that** "*Each response organization "shall prepare a general plan or plans for coordinating and [performing their assigned functions as specified in Section 4] …..*"
	In addition, the following paragraphs provide basis for this recommendation: **GS-R-2, paras. 5.7, 5.8, 5.9, 5.10, 5.11, 5.14, 5.21, 5.22, 5.25, 5.31, 5.33, 5.37, 5.39**
R22	**Recommendation: SORNS should develop its own emergency arrangements consistently with IAEA Safety Standards to fulfill its roles in emergency response.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The roles of SORNS to organize and supervise environmental monitoring and to coordinate and direct the efficiency control of decontamination carried out by authorized TSOs in an emergency may result in a conflict of interest. Namely, the authorized TSOs act at the same time as support to SORNS and/or to an operator and as a response organization as well. This may diminish the roles of other response organizations (such as the Ministry of Environment or Protection and Rescue Directorate).
(1)	**BASIS: GS-R-2 para.5.10 states that** "*In planning for, and in the event of [a nuclear or radiological emergency], the regulatory body shall act as an adviser to the government and [response organizations] in respect of nuclear safety and radiation protection.*"
	BASIS: GSR Part 1: 2.22 states that*"The government shall designate competent authorities that will have the responsibilities and resources necessary to make preparations and arrangements for dealing with the consequences of incidents in facilities and activities that affect, or that might affect, the public and the environment."* **BASIS: GSR Part 1: 2.9 states that** "*No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities."*
S16	**Suggestion: The Government should consider reviewing and revising the roles and responsibilities assigned to SORNS in emergency response in order to avoid compromising SORNS regulatory responsibilities and taking into account IAEA Safety Standards as well as the responsibilities of other State bodies and organizations.**

10.5. SUMMARY

SORNS has been given the authority to approve and supervise operator's emergency arrangements and to carry out inspections over implementation of the 2013 Act and subordinate regulations and ordinances in this regard. However, the current regulations and ordinances do not comprehensively cover all the necessary functions to be performed by operators in an emergency response and the infrastructure to be put in place by them as required in IAEA Safety Standards (GS-R-2). Moreover, SORNS does not

perform inspections over operators' emergency arrangements and does not evaluate any of their exercises. Thus, there is necessity for SORNS to strengthen its regulatory framework in EPR.

SORNS has a range of roles and responsibilities in response to a nuclear or radiological emergency. These roles vary from acting as adviser to the Government and response organizations in an emergency consistently with IAEA Safety Standards (GS-R-2, GSR Part 1) and acting as a national competent authority under Early Notification and Assistance Conventions to provider of public information to taking active role in the emergency response on-site and off-site as a response organization. While SORNS has been equipped to fulfil these roles and has a dedicated emergency centre, it has not fully established its own emergency plan and procedures to ensure it will respond effectively in an emergency. At national level, the roles of SORNS may need to be revised taking into account IAEA Safety Standards. Notwithstanding this, SORNS need to establish comprehensive emergency arrangements (plans, procedures, emergency management organization, staffing plan, training and exercise programmes, quality assurance programme etc.) to comply with IAEA Safety Standards in EPR (GS-R-2, GS-G-2.1, GSG-2).

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

The Croatian regulatory framework for radiation protection with regards to medical exposure is covered by:

- Act on Radiological and Nuclear Safety (OG 141/13, 39/15);
- Ordinance on the conditions for application of ionizing radiation sources in medicine and dentistry (OG 89/13);
- Ordinance on the conditions and measures of ionizing radiation protection for performing operations involving electrical devices generating ionizing radiation (OG 41/13);
- Ordinance on the conditions and measures of ionizing radiation protection for performing operations involving radioactive sources (OG 41/13);
- Ordinance on the training required for handling ionizing radiation sources and the implementation of measures for protection against ionizing radiation (OG 63/11);
- Ordinance on dose limits (OG 59/13).

There are two authorities responsible for radiation protection and safety related to medical exposures: The Ministry of Health and SORNS.

Most of the IAEA requirements of GSR Part 3 related to medical exposure are covered in the Croatian legislative framework and establish responsibilities of SORNS and the licensees, technical requirements, diagnostic reference levels (DRLs), dose constraints for carers, conditions for release of patient undergoing therapy with unsealed sources, etc. In establishing these regulations, SORNS collaborates with the Ministry of Health and with some scientific and professional bodies, but the collaborations with professional bodies are not formalized.

The principles of justification and optimization are globally included in the Croatian legislation; however, some non-compliances with GSR Part 3 requirements, identified and reported by the counterpart in SARIS self-assessment, was confirmed by the IRRS team. Some of these non-compliances have not been taken into account in the suggested plan prepared by SORNS.

The major issue identified by the IRRS team is that the full scope of medical exposures, as defined in GSR Part 3, is not covered during neither the assessment of the application submitted for authorization nor the inspection process carried out by SORNS. Confirmation of this issue was noted during the inspection observed by the IRRS team members. Furthermore, there is no specialization in medical physics and insufficient provisions regarding the responsibilities of medical physicists. Medical physicists play an essential role in patient protection from undue exposure and in the reduction of patients' doses, especially in the high risk activities such as radiotherapy, nuclear medicine and interventional radiology.

Responsibilities of the government and of the regulatory body specific to medical exposure:

The responsibilities of the Government in relation to medical exposure are defined and the relevant parties are notified of their responsibilities. However, some regulatory requirements[6] do not explicitly assign responsibilities for generic justification and periodical review of radiological procedures to the health authority, in collaboration with appropriate professional bodies. The IRRS team was not given evidence either of generic or specific justification documentation, nor of which organization is responsible for the process of defining and reviewing the justification criteria.

[6] such as Article 4 of OG 89/13 that requires "all new types of diagnostic, intervention or therapeutic examinations or procedures involving the use of ionizing radiation sources in medicine and dentistry shall be justified in advance before being generally adopted".

In addition, the IRRS team noted that the effective implementation of the requirements related to justification and referral criteria in OG 89/13 are not checked by SORNS.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The existing legislation does not clearly assign the responsibilities for justification of radiological procedures. As a result, there is no evidence that only justified practices are authorized. Cooperation between SORNS, the Ministry of Health and the professional bodies is not optimal and the consultation process with professional bodies is not formalized. Furthermore, some guidelines, such as those regarding patient release or referral criteria, which should be established by the Ministry of Health, are not yet available.
(1)	**BASIS: GSR Part 3 Requirement 34, para. 3.147 states that** *"The government, in accordance with paras 2.13–2.28, shall ensure with regard to medical exposures that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the relevant parties identified in paras 2.40 and 2.41 are authorized to assume their roles and responsibilities, and shall ensure that they are notified of their duties in relation to protection and safety for individuals undergoing medical exposures."*
(2)	**BASIS: GSR Part 3 Requirement 10, para. 3.16 states that** "*The government or the regulatory body, as appropriate, shall ensure that provision is made for the justification of any type of practice and for review of the justification, as necessary, and shall ensure that only justified practices are authorized."*
(3)	**BASIS: GSR Part 3 Requirement 36, para. 3.151 states that** *"Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:* *(a) It is a radiological procedure that has been requested by a referring medical practitioner and information on the clinical context has been provided, or it is part of an approved health screening programme;* *(b) The medical exposure has been justified by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or it is part of an approved health screening programme;* *(...)."*
(4)	**BASIS: GSR Part 3 Requirement 37, para. 3.156 states that** *"Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments."*
(5)	**BASIS: GSR Part 3 Requirement 37, para. 3.158 states that** "*Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure."*
(6)	**BASIS: GSR Part 3 Requirement 34, para. 3.149 states that** *"The government shall ensure that, as a result of consultation between the health authority, relevant professional*

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	bodies and the regulatory body, the following are established: *(b) Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources." (...)"*
R23	**Recommendation: SORNS, in coordination with the Ministry of Health, should initiate arrangements for assigning responsibilities for justification. SORNS should also ensure that only justified practices are authorized.**
R24	**Recommendation: The Ministry of Health and SORNS should issue the necessary guidelines, in cooperation with the relevant professional and scientific bodies, in accordance with the requirement of GSR Part 3.**

OG89/13 requires that health professionals with responsibilities for medical exposure are suitably qualified; SORNS does check this requirement during the licensing process. Unfortunately, there is no specialization in medical physics and no recognition of this profession at a national level.

Furthermore, there are insufficient provisions in the current regulatory framework on the responsibilities of medical physicists and the cooperation between medical practitioners and medical physicists during the optimization process, including: planning and controlling the patient dose during radiotherapy or nuclear medicine procedures and involvement of medical physicists in the establishment of quality assurance programme or in patient release.

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	Observation: There is no specialization in medical physics, and the IRRS team has been informed that there are not enough medical physicists available in Croatia to implement the radioprotection of patients consistent with the requirements of the IAEA. In addition, the responsibilities of medical physicists, as set in GSR Part 3, are not fully defined in the Croatian regulations.
(1)	**BASIS: GSR Part 3 Requirement 35, para. 3.147 states that** *"The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they fulfill the requirements for education, training and competence in the relevant specialty."* **BASIS: GSR Part 3 Requirement 35, para. 3.150 states that** "*The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (...medical physicists, (...) and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they:* *(a) Are specialized in the appropriate area;* *(b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32;* *(c) Are named in a list maintained up to date by the registrant or licensee."*

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(2)	**BASIS: GSR Part 3 Requirement 35, para. 3.164 states that** *"For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, shall ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances."*
(3)	**BASIS: GSR Part 3 Requirement 35, para. 3.165 states that** *"For therapeutic radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, (…), shall ensure that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered, so that the radioactivity is primarily localized in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable."*
R25	**Recommendation: The Government should recognize medical physicists as a profession at a national level and develop specialization in medical physics with objective to ensure the radiation protection of patients.**
R26	**Recommendation: SORNS should review its regulation to supplement the responsibilities of medical physicists so that they are fully integrated in all medical practices in accordance with GSR Part 3.**

Responsibilities for overall protection of the patient and the carers and for information on radiation risks

Dose constraints for carers and comforters are established but there is no regulatory requirement to provide them with information on the radiation risks prior to providing care. There are also no regulatory provisions to provide information on the radiation risks to breast feeding women prior to undergoing diagnostic or therapeutic procedures.

More generally, the Act on Patient Rights (OG169/04, 37/08) mentions that patients should be given information on request but there is no obligation to systematically inform patients on radiation risks, except in some cases such as biomedical research.

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	Observation: There is no legal obligation for licensees to systematically inform patients, carers and comforters about radiation risks.
(1)	**BASIS: GSR Part 3 Requirement 36 para. 3.151 states that** *"Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:* *(d) The patient or the patient's legal authorized representative has been informed as appropriate of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.*
(2)	**BASIS: GSR Part 3 Requirement 36, para. 3.153 states that** *"Registrants and licensees*

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	shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure. (...)"
(3)	**BASIS: GSR Part 3 Requirement 39, para. 3.175 states that** *"Registrants and licensees shall ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate, to request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that:* *(a) She is or might be pregnant;* *(b) She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical."*
S17	**Suggestion: SORNS should consider making provisions for informing carers, comforters and patients, in particular breast feeding women, about the radiation risks, in accordance with GSR Part 3.**

Optimization

The regulatory framework includes most of the IAEA requirements regarding optimization, quality assurance (QA), quality control (QC), but the implementation of these obligations are not comprehensively checked by SORNS.

Furthermore, the IRRS team identified that some requirements of GSR Part 3 are not covered in the Croatian legislation, especially requirements on:

1. **Calibration**

For example there are no mandatory requirements for:

- calibrations at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body;
- independent verification of calibrations of radiotherapy units prior to clinical use;
- measurements of physical parameters of medical radiological equipment after any installation of new software or modification of existing software that could affect protection and safety of patients;
- calibration of dosimeters used for patient dosimetry and traceability of sources to a standards dosimetry laboratory;
- calibrations of electrical devices generating ionizing radiation by or under the supervision of medical physicists, whose involvement should be determined by the complexity of the procedures and the associated radiation risks.

2. **Quality Assurance**

For example there are no mandatory requirements for:

- medical physicists to be involved in the establishment of a QA programme;

- licensee to ensure independent audits of the QA programme and their periodical review in accordance with the complexity of the radiological procedures and the associated risks;
- documented delegation of responsibilities by each principal party.

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	Observation: The regulatory framework regarding optimization, such as calibration, quality assurance and involvement of medical physicists in all medical practices with radiation exposure, is not fully in line with the requirements of GSR Part 3. As a result, patients may be exposed to undue radiation doses**.** SORNS does not verify through independent review, assessment or inspection process that all aspects of optimization are implemented**.**
(1)	**BASIS: GSR Part 3 Requirement 38, para. 3.167 states that** "*In accordance with para. 3.154(d) and (e), the medical physicist shall ensure that:* *(b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body;* *(c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use;* *(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory."*
(2)	**BASIS: GSR Part 3 Requirement 38, para. 3.170 states that** "*Registrants and licensees, in applying the requirements of these Standards in respect of management systems, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate."*
(3)	**BASIS: GSR Part 3 Requirement 38, para. 3.171 states that** *"Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility:* (a) *Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist:* *(i) At the time of acceptance and commissioning of the equipment prior to its clinical use on patients;* *(ii) Periodically thereafter;* *(iii) After any major maintenance procedure that could affect protection and safety of patients;* *(iv) After any installation of new software or modification of existing software that could affect protection and safety of patients (…)"*
(4)	**BASIS: GSR Part 3 Requirement 38, para. 3.172 states that** "*Registrants and licensees shall ensure that regular and independent audits are made of the programme of quality*

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	assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks".
(5)	**BASIS: GSR Part 3 Requirement 36, para. 3.154 states that** *"Registrants and licensees shall ensure that:(…)* *(f) Any delegation of responsibilities by a principal party is documented."*
R27	**Recommendation: SORNS should ensure that the existing requirements for optimization are fully implemented in all medical practices and that requirements regarding responsibilities of medical physicists, quality assurance, quality control and calibration are in accordance with the IAEA standards.**

Reviews and records

Many requirements related to the process of review and assessment are included in the Croatian regulation, but there are no mandatory requirements for licensees to:

- conduct, at approved intervals, local assessments of patients' doses with regard to DRL, for those radiological procedures for which DRL have been established;
- perform a radiological review if patient doses fall substantially below the relevant DRL and the exposures do not provide useful diagnostic information.

The review of appropriate implementation of DRL by the licensees is not part of SORNS' licensing or inspection process.

Many of the requirements related to records are covered in the Croatian legislation, but some obligations are not specified, in particular:

- formalization of delegation of responsibilities;
- keeping some calibration records;
- exposure records of volunteers involved in biomedical research programmes;
- local DLR assessments and reviews;
- records of the number of exposures in case of diagnostic radiology or image guided interventional procedures to conduct a retrospective assessment of doses.

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	Observation: The IRRS team notices that there is no requirement for: • periodical assessment of patients' doses with regard to diagnostic reference levels; • review when doses are substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient; • internal radiological review of the radiation protection practices by licensees. As a result, patients may not be adequately protected**.** Some records to be kept are not specified in the legislation, especially those regarding the formalization of delegation of responsibilities and certain calibration and exposure records.

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(1)	**BASIS: GSR Part 3 Requirement 42, states that** *"Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained.(…). The radiological review shall include an investigation and critical review of the current practical application of the radiation protection."*
(2)	***BASIS: GSR Part 3 Requirement 38, para. 3.169*** **states that** *"Registrants and licensees shall ensure that:* *(a) Local assessments, on the basis of the measurements required in para. 3.168, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established (para. 3.148).* *(b) A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure:* *(…)* *(ii) Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient."*
(3)	**BASIS: GSR Part 3 Requirement 42, para. 3.183 states that** *"Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel records:* *(a) Records of any delegation of responsibilities by a principal party (as required in para. 3.154(f));* *(…)."*
(4)	**BASIS: GSR Part 3 Requirement 42, para. 3.184 states that** *"Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance:* *(a) Records of the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients;* *(d) Records associated with the quality assurance programme, as required in para. 3.171(d)."*
(5)	**BASIS: GSR Part 3 Requirement 42, para. 3.185 states that "***Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records for medical exposure:* *(a) For diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures;* *(b) For image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired;*

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	(…) *(e) Exposure records for volunteers subject to medical exposure as part of a programme of biomedical research."*
R28	**Recommendation: SORNS should ensure that the existing requirements for reviews and records related to medical exposure are implemented in all medical practices and supplement its Ordinances to improve assessment and recording of patient doses in accordance with GSR Part 3.**

Unintended and accidental medical exposures

Most of the requirements related to the prevention of unintended medical exposures, and their resulting investigations, are included in the Croatian legislation, except those regarding:

- incidents due to software failure, or system failure, accident, error, other unusual occurrence with the potential for subjecting the patient to an unintended exposure;
- indication of the corrective actions required to prevent the recurrence of an unintended or accidental medical exposure.

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	Observation: Ordinance 89/13 does not cover some of the requirements of GSR Part 3 regarding unintended and accidental medical exposure. Furthermore, SORNS has not developed a procedure for notification by the licensees, and the IRRS team has been informed that SORNS has not received unintended exposure notification to date. Moreover, unintended exposure records are not checked during inspections.
(1)	**BASIS: GSR Part 3 Requirement 41, para. 3.180. states that** *" Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures:* *(f) Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended."*
(2)	**BASIS: GSR Part 3 Requirement 41, para. 3.181 states that** "*Licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.180:* *(b) Indicate the corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure;* *(d) Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a)–(c) above, as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or as otherwise required by the regulatory body, submit this written record, as soon as possible, to the regulatory body, and to the relevant health*

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	authority if appropriate."
R29	**Recommendation: SORNS should ensure that all requirements related to unintended and accidental medical exposure are implemented in compliance with the requirement of GSR Part 3.**
S18	**Suggestion: Since SORNS has not received any unintended or accidental exposure reports to date, SORNS should consider supporting this notification process through developing guidelines or/and training of medical staff and medical physicists.**

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and Regulatory Framework

In Croatia, the regulatory framework is set down in the Act on Radiological and Nuclear Safety (OG 141/13) and the Act on Occupational Health and Safety (OG 71/14) and a range of Ordinances.

The Act on Radiological and Nuclear Safety (OG 141/13) lays down the basis for preventing and limiting the health hazards and other detrimental effects of radiation. This Act covers the use of radiation and other practices that involve or may involve exposure to radiation hazardous to human health. The 2013 Act also establishes the State Office for Nuclear and Radiological Safety (SORNS) as the competent body or regulatory body for activities pertaining to radiological safety and occupational radiation protection and assigns to it a range of tasks and responsibilities.

Under the legislation a system of approvals for the performance of operations involving ionizing radiation sources and licenses for the use of ionizing radiation sources is operated by SORNS and exemption criteria from these requirements is also described. The regulatory system encompasses the principles of radiological safety i.e. justification, optimization and dose limitation. Dose limits are set down for workers, trainees, students, apprentices and members of the public. Under the regulatory system, requirements are set down covering protection during pregnancy and breastfeeding, personal dose monitoring and recording of occupational exposures, medical fitness for work, appointment of a person responsible for protection against ionizing radiation (RPO), medical exposures, educational institutions and professional training of persons involved in work with sources of ionizing radiation, the roles and responsibilities of approval and licence holders and the authorized professional technical services (TSO).

SORNS as the regulatory body enforces the requirements to ensure that occupational radiation protection and safety is optimized, and that dose limits for occupational exposure are complied with. It also enforces requirements for the monitoring and recording of occupational exposures in planned exposure situations and has in place a regulatory strategy for controlling exposure in existing exposure such as exposure of aircrew to cosmic radiation and exposure of workers to radon in workplaces. SORNS also authorizes the TSOs.

The regulatory framework in Croatia for occupational radiation protection includes SORNS, the holders of licences for practices involving ionizing radiation sources, Technical Services Organizations (TSOs), the Croatian Institute for Health Protection and Safety at Work and the Medical Institutions that are authorized to perform medical fitness to work of exposed workers.

General responsibilities of employers, registrants and licensees

Under the Croatian regulatory system, licensees and users are responsible for the protection of workers against occupational exposure and shall ensure that protection and safety is optimized and that the dose

limits for occupational exposure are not exceeded. They must implement a radiation protection and safety programme based on a risk analysis and apply radiation protection and safety measures commensurate with the risks associated with the practice or activity. Under Croatian legislation, both the risk analysis and the radiation and safety programme must be submitted to SORNS and risk analysis must be verified by a Technical Service Organisation (TSO). Dose limits consistent with the IAEA Standard GSR Part 3 are in place for occupational exposure of workers, members of the public, persons undergoing training or education for working with sources of ionizing radiation, emergency interventions and for supervised and controlled areas. The dose limit for the lens of the eye will be revised in line with the IAEA Standard GSR Part 3 as part of the transposition of the new EC Directive 2013/59.

Licensees and users are responsible for making arrangements for assessment and recording of the occupational exposure and for workers' health surveillance, and they must provide workers with adequate information, instruction and training in radiation protection and safety. Initial training and refresher training of exposed workers or persons trained to work with sources of ionizing radiation is mandatory by law and evidence of all training must be made available to SORNS.

Workplace monitoring by licensees using calibrated radiation survey and contamination meters is not required for all practices under the Croatian regulatory system, in the event of a TLD being lost or damaged, for the licensee to estimate the dose for the exposed worker and to record it as an estimated dose in the personal dose record of the worker. Therefore, SORNS should consider revising Article 23 (3) of the Ordinance on Measurement of Personal Doses, Examination of Ionizing Radiation Sources and Working Conditions and on Reports and Registers (OG 41/12) in accordance with IAEA Safety Guide RS-G-1.3.

Licensees and users are responsible for medical surveillance of exposed workers and persons trained to work with sources of ionizing radiation and this must be carried out by Medical Institutions which practice occupational medicine and which are authorized by the Minister competent for Health. Licensees and users must make special arrangements for female workers, as necessary, for radiological protection of the embryo or foetus and of breastfeeding infants. Licensees and users must also make special arrangements for the radiological protection and safety for persons under 18 years of age who are undergoing training.

Licensees and users must appoint a Radiation Protection Officer (RPO) with responsibility for implementing the radiation protection and safety measures. Licensees and users must also cooperate to the extent necessary for compliance by all responsible parties with the requirements for radiological protection and safety and in particular in the case of Outside Radiation Workers.

Under Croatian legislation, monitoring of the occupational exposure of workers is one of the professional tasks in radiation protection that is assigned to TSOs under an authorization granted by SORNS. All exposed workers in Croatia must be registered with SORNS and the results of all personal dosimetry measurements are forwarded by the authorized TSOs to SORNS and retained in the Croatian National Dose Register. Currently only $Hp(10)$ is being measured in Croatia as no TSO is authorized to measure $Hp(0.07)$ or conduct internal dosimetry. With the introduction of the new dose limit for the lens of the eye in 2018 a national capability will be required to assess $Hp(0.07)$ and $Hp(3)$. The development of the radwaste management programme will also require a capability for internal dosimetry.

All dose estimates are carried out by the TSOs and all records of doses are maintained by SORNS. Under Croatian legislation there is no classification of exposed radiation workers into Category A or B and all personal dosimeters must be replaced at one month intervals.

General responsibilities of workers

The obligations and responsibilities of workers in terms of occupational radiation protection are set down in the legislation and workers must fulfil their obligations and carry out their duties for protection and safety. Exposed workers must implement all radiation protection and safety measures to protect both themselves and all other workers.

Requirements for radiation protection programmes

Licensees and users must implement a radiation protection and safety programme based on a risk analysis and apply radiation protection and safety measures commensurate with the risks associated with the practice or activity. They must also appoint a Radiation Protection Officer (RPO) with responsibility for implementing the radiation protection and safety measures.

Licensees and users must establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas consistent with the IAEA BSS Standard and they must establish local rules, written instructions or radiation safety procedures.

Licensees and users are responsible for making arrangements for the assessment and recording of occupational exposures, workplace monitoring and for workers' health surveillance, and they must provide workers with adequate information, instruction and training in radiation protection and safety. In the specific case of emergency workers there is a need for clarity on what constitutes an emergency worker.

In terms of existing exposure situations, SORNS has in place a regulatory strategy for cosmic radiation exposure of aircrew and for exposure to radon in workplaces.

The current regulatory strategy for controlling exposure to cosmic radiation and radon in work places is prescribed in Ordinance OG 121/13 and allows for the designation of radiation exposed workers and the radiation protection system for practices applies.

Monitoring programmes and technical services

Under Article 42 of the Act on Radiological and Nuclear Safety (OG 141/13) tasks pertaining to radiological safety shall be performed by a TSO authorized by SORNS and the current professional tasks of protection against ionizing radiation that are authorized by SORNS include:

- (Personal Dosimetry) - measurement of personal dose of external irradiation of exposed workers, apprentices or students undergoing training or education for working with ionizing radiation sources;
- (QA and Risk Assessment) - testing X-ray sets, accelerators and any other apparatuses emitting ionizing radiation, and providing opinions including risk assessments based on measurements and calculations;
- (QA and Risk Assessment) - testing sealed radioactive sources, apparatuses with sealed radioactive sources, open radioactive sources and providing opinions including risk assessments based on measurements and calculations;
- (Monitoring and Shielding Assessment) - testing the premises where sources of ionizing radiation are used and preparing documents which demonstrate whether the premises concerned comply with the prescribed requirements for protection against ionizing radiation;
- (Environmental Monitoring) - testing and monitoring types and activities of radioactive substances in the air, soil, sea, rivers, lakes, ground waters, precipitation, drinking water, foodstuffs and general use products;
- (Radon Monitoring) - testing the concentration of radon and radon progeny in the air.

The authorization issued by SORNS for carrying out these professional tasks of protection against ionizing radiation is conditional on the expert technical service having among others:

- at least two staff with a university degree and a minimum of five years of experience in performing ionizing radiation protection tasks, of whom one with completed undergraduate and graduate university studies or integrated undergraduate and graduate university studies or specialist professional graduate studies in natural science (field of physics);
- made arrangements for measuring personal doses and for monitoring the health of workers handling sources of ionizing radiation, and for their special professional training in the implementation of protection measures against ionizing radiation;
- measuring instruments and other equipment necessary for performing the tasks for which authorization is requested, calibrated in accordance with positive regulations;
- description of the procedures (methodology) involved in the performance of the tasks for which authorization is requested;
- valid accreditation in accordance with the requirements of the HRN EN ISO/IEC 17025 standard for the measurement method which is necessary, pursuant to Article 5, for the performance of those professional tasks of protection against ionizing radiation for which authorization is requested.

SORNS has not conducted any post-authorization inspection or assessment of any of the three authorized TSOs in Croatia to establish whether they still comply with the prescribed requirements of their authorizations.

During this IRRS mission, experts visited the facility of an authorized TSO in Zagreb and noted that the technical/scientific staff is educated to a high level and that the TSO has a range of calibrated equipment to perform its authorized activities. It was also noted however, that the staff do not have any formal training in radiation protection at the level of post-graduate. They have evidence of having attended some short and specific training courses, but such training is significantly less than that required of a as Qualified Expert described in the IAEA Safety Standards and in particular in GS-G 1.4.

The TSO conducts routine performance testing of its TLD System to test the accuracy and precision of the dosimetry system for measurement of doses at a single energy and performs daily QC checks to monitor specific aspects of system performance. However, SORNS has not specified any on-going re-approval performance tests for the TLD System other than for the TSO to participate in intercomparison exercises and to maintain its ISO 17025 measurement accreditation. To date only one intercomparison exercise has been conducted by SORNS.

As a consequence of the important radiation protection advisory role that TSOs are currently playing in the regulatory process in Croatia, the process for authorizing TSOs and the requirements for authorization should be expanded to incorporate a requirement for TSOs to demonstrate competence as a recognized Qualified Expert consistent with the IAEA Safety Standards.

During this IRRS mission, experts accompanied an Inspector from SORNS to the facility of an Industrial Radiography Company in Zagreb. This licensee has a purpose built radiography bay for X-ray radiography, but three HASS sources are also stored in the bay. The inspection was mainly administrative in nature and was conducted in a very professional and efficient manner. However, it was noted that the Inspector had limited radiation protection training and experience in the high-risk practice of industrial radiography.

Currently, SORNS does not have the required staff with the required level of expertise to assess the work of the TSOs particularly in relation to QA, Risk Assessments, TSO Opinions and Personal Dosimetry.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: One of the tasks and responsibilities assigned by the Government to SORNS is to authorize and supervise the professional operations of authorized TSO. No post-authorization inspection or assessment of any authorized TSO in Croatia has ever taken place to establish that the authorized TSO still complies with the prescribed requirements of its authorization. The formal recognition of Qualified Experts is absent.
(1)	**BASIS: GSR Part 1 Requirement 27, states that** "*The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.*"
R30	**Recommendation: SORNS should put in place a programme of inspection of authorized TSOs as part of their annual inspection programme to establish that all authorized TSOs are maintaining the prescribed requirements of their authorizations.**
(2)	**BASIS: GSR Part 3 Requirement 2, para 2.21(b) states that** *"The government shall ensure that requirements are established for the formal recognition of qualified experts."*
R31	**Recommendation: SORNS should initiate in consultation with the relevant government departments and state agencies the development of a formal recognition for qualified experts and an additional requirement for TSOs to have a qualified expert on their staff should be included in SORNS process for authorizing TSOs.**

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	Observation: Emergency Exposure Situations - There is no documented programme for managing, controlling and recording the occupational doses received by emergency workers in an emergency. SORNS, in line with the legislation and regulations does not consider an emergency worker under the definition of an exposed worker nor is it defined as to who is to be regarded as an emergency worker. An emergency worker needs to be defined consistently with IAEA safety standards (GSR Part 3).
(3)	**BASIS: GSR Part 1 Requirement 45, para. 4.12 states that** *"The government shall establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers, which shall be implemented by response organizations and employers."*
R32	**Recommendation: The Government should define the concept of an emergency worker taking into account the IAEA safety standards and should establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers. This programme should be implemented by response organizations, licensees and SORNS.**

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	Observation: Existing Exposure Situations – Cosmic Exposure of Aircrew and exposure to radon in work places. The current regulatory system for controlling exposure to cosmic radiation and exposure to radon in work places requires the full implementation of the radiation protection system for practices once exposed workers are identified.
(4)	**BASIS: GSR Part 3 Requirement 5.24 states that** *"The requirements in respect of occupational exposure in existing exposure situations (paras5.25–5.33) apply to any occupational exposure arising from the situations specified in para. 5.1."*
(5)	**BASIS: GSR Part 3 Requirement 52, para. 5.29 states that** *"If, despite all reasonable efforts by the employer to reduce radon levels, the activity concentration of 222Rn in the workplace remains above the reference level established in accordance with para. 5.27, the relevant requirements for occupational exposure in planned exposure situations as stated in Section 3 shall apply."*
S19	**Suggestion: SORNS should consider reviewing and revising its regulatory system for existing exposure situations with a view to implementing only those relevant requirements for occupational exposure of exposed workers.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There is no requirement in Croatian legislation that in the event of a TLD being lost or damaged, that a dose to an exposed worker should be estimated and that the estimated dose should be recorded in the personal dose record of the worker as an estimated dose. In addition, the absence of a requirement for workplace or area monitoring to be conducted by licensees using calibrated radiation survey meters will makes such dose assessments difficult.
(6)	**BASIS: IAEA Safety Series RS-G-1.3 Section 8 para. 8.3 states that** *"If a dose assessment is not available for a period when a radiation worker was (or should have been) monitored — which may happen when a dosimeter has been damaged or lost, or recorded a dose that, on investigation, is declared invalid — the record keeping system should allow the introduction of doses estimated or assessed by an authorized person. These dose estimates should be marked in such a way that they can be distinguished from official dose measurements made by the approved monitoring service."*
S20	**Suggestion: SORNS should consider revising Article 23 (3) of the Ordinance on Measurement of Personal Doses, Examination of Ionizing Radiation Sources and Working Conditions and on Reports and Registers (OG 41/12) in accordance with IAEA Safety Guide RS-G-1.3 Section 8.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Currently only *Hp*(10) is being measured in Croatia as no TSO is authorized to measure *Hp*(0.07) or conduct internal dosimetry. With the introduction of the new dose limit for the lens of the eye in 2018, a national capability will be required to assess *Hp*(0.07) and *Hp*(3). The development of the radwaste management programme will also require a capability for internal dosimetry.
(7)	**BASIS: IAEA Safety Series RS-G-1.3 Section 3.10 states that** *"An individual monitoring service approved by the regulatory authority should be used. The regulatory authority should require such a service to supply dosimeters capable of measuring Hp(10) and Hp(0.07) with adequate accuracy for all relevant radiation type."*
S21	**Suggestion: SORNS, in light of the introduction of the new dose limit for the lens of the eye and the development of the radwaste management programme, should consider introducing arrangements so that a national capability for extremity dose assessment *Hp*(0.07) and *Hp*(3) together with a national capability for internal dosimetry is available. The relevant ordinance on Measurement of Personal Doses, Examination of Ionizing Radiation Sources and Working Conditions and on Reports and Registers (OG 41/12) should be revised in accordance with IAEA Safety Guides.**

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

11.3.1. CONTROL OR RADIOACTIVE DISCHARGES AND MATERIALS FOR CLEARANCE

Croatian legislation addressing setting discharge limits, include:

- Regulation 44/08 on the conditions and method of disposal of radioactive waste, spent sealed radioactive sources and ionizing radiation sources which are not intended for further use;
- Ordinance 41/13 on the conditions and measures of ionizing radiation protection for performing operations involving radioactive source; and
- Ordinance 71/12 on authorizations and licences for use and movement of ionizing radiation sources.

SORNS noted that there are current issues linked to radioactive discharges, including:

- effluents generated by the nuclear medicine treatment activities (the effluents from the isolation room of patients treated for thyroid carcinoma) are collected in the decay tanks and after a decay time released in the general sewerage system;
- effluents generated by the nuclear medicine diagnosis activities are directly discharged in the sewerage of the hospitals without control measurements; there is no annual reporting of the estimated amount of discharged activity; and
- information is now being requested from hospitals as to the radioactivity levels from their releases.

SORNS also informed that monitoring of hospital discharges stopped two years ago, and a decision needs to be taken as to whether it is to resume.

WS-G-2.3 §3.43 states that 'a review of the authorization should be conducted whenever modification of the plant or of its operational conditions is expected to affect significantly the characteristics or regime of radioactive discharges'. It is therefore important to review periodically authorized discharges. Changes in hospital activity may result in higher radioactive discharge levels. Recording the estimated amount of discharged activity annually would provide an indication of changes in hospital activities.

The Regulation 44/08 requires attention. The regulation does not support the approach stated in WS-G-2.3 with regards to discharge limits. No discharge limits are currently set, imposed on licences or monitored for compliance. Other deficiencies include:

- Article 15 makes reference to the old BSS 96/29/EURATOM clearance;
- Article 27 focuses on management of liquid radioactive waste discharges based on the volume being handled. No information is provided for treatment of liquid discharges if they are less than 200 l/day;
- Article 38 refers to radioactive waste being discharged to the environment, when in fact it should say 'radioactive waste can be cleared from regulatory control;
- Article 42 enables the release of low level liquid discharges on the basis of the environmental impact study and makes reference to the environmental impact assessment committee. It is however not said who is to do this assessment, nor what are the regulatory clearance levels. In addition no committee was ever set up;
- Article 43 requires gaseous releases of short-lived radionuclides to be prevented by the installation of suitable filters without any further information;
- Article 50 refers to an inventory must be prepared by the licensee as well as annual reporting on radioactive waste discharged into the environment. This is not being enforced by SORNS.

Ordinance 41/13 makes reference to clearance levels for solid waste. These clearance levels equate the exemption activity levels, as set in the new BSS EU Directive 2013/59 and RS-G-1.7.

SORNS' intention is to have all ordinances compliant with the new BSS EU Directive 2013/59 by 2018

In terms of clearance levels of solid radioactive waste, SORNS has adopted to use the exemption levels of 10 μSv/year and the activity levels found in RS-G-1. The IRRS team noted that this is in line with IAEA standards.

Figure 3 of the WS-G-2.3 states that 'authorized discharge limits should never lead to source-related doses exceeding the upper value for the dose constraint and not normally exceeding the dose constraint itself'. GSR Part 3 Requirement 31 on radioactive waste and discharges states that 'relevant parties shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization'.

In the new Ordinance 71/12 a risk analysis is to be carried out by authorized users. Its Annex XVI provides 'instructions for preparing the risk analysis', but points:

- 2.6 Procedure for handling radioactive waste and its disposal and the method of discharge of radioactive substances into the environment, and
- 4.3 Assessment of irradiation of a critical group of population resulting from performing the practice involving ionizing radiation sources and the disposal of radioactive waste are very generic.

Since risk analyses are currently being requested by licensees, the IRRS team was not able to verify whether these instructions are sufficient to receive the detailed rationale needed to derive discharge limits from dose constraints for members of the public after optimization process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Regulation 44/08 does not address limits for liquid and gaseous radioactive discharges in accordance with IAEA standards. As a result, radioactive discharge limits are not imposed on licences and protection of the public cannot be verified. There is also no procedure for establishing dose constraints to be used in the optimization of protection and safety for public exposure, which is required to derive discharge limits.
(1)	**BASIS: GSR Part 3 Requirement 11, para. 3.22 states that** *"The government or the regulatory body:* *(a) Shall establish and enforce requirements for the optimization of protection and safety;* *(b) Shall require documentation addressing the optimization of protection and safety;* *(c) Shall establish or approve constraints on dose and on risk, as appropriate, or shall establish or approve a process for establishing such constraints, to be used in the optimization of protection and safety."* **BASIS: GSR Part 3 Requirement 11, para. 3.122 states that** *"Before authorization of a new or modified practice, the regulatory body shall require the submission of, and shall review, the safety assessments (paras 3.29–3.36) and other design related documents from the responsible parties that address the optimization of protection and safety, the design criteria and the design features relating to the assessment of exposure and potential exposure of members of the public."*
(2)	**BASIS: GSR Part 3 Requirement 14, para. 3.37 states that** "*The regulatory body shall establish requirements that monitoring and measurements be performed to verify compliance with the requirements for protection and safety. The regulatory body shall be responsible for review and approval of the monitoring and measurement programmes of registrants and licensees."*
(3)	**BASIS: GSR Part 3 Requirement 29, para. 3.123 states that** "*The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges."*
(4)	**BASIS: GSR Part 3 Requirement 31, states that** *"Relevant parties shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization."*
R33	**Recommendation: SORNS should review their regulatory framework with regards to liquid and gaseous radioactive discharges and ensure the optimization of protection and safety is achieved and discharge limits imposed on licences that cover such discharges.**

11.3.2. ENVIRONMENTAL MONITORING

There is one main Ordinance that deals with environmental monitoring, i.e. Ordinance 121/13 'on the environmental monitoring of radioactivity'. However the IRRS team has identified issues of non-compliance with IAEA standards:

- there is a no clear difference between requirements for source and environmental monitoring,

- there is no differentiation between registrants and licensees, and
- the terms used are not consistent with IAEA standards.

There is a need to adapt the Ordinance to reflect the approach described in RS-G-1.8. This will result in clearer and more transparent requirements being set for both regulator and operator.

Although facility environmental monitoring (i.e. source monitoring) programme is required, it has not been implemented by licensees. SORNS informs that enforcement of this requirement will be implemented once risk analysis from each licensee is received (as required by Ordinance 71/12 on authorizations and licences for use and movement of ionizing radiation sources).

RS-G-1.8 details environmental and source monitoring for purposes of radiation protection. Monitoring programmes are described, together with their related issues, with different requirements set under normal practice, emergency or chronic scenarios.

§ 3.5 states that: "the regulatory body should (a) establish technical requirements for monitoring arrangements, including arrangements for emergency monitoring and quality assurance, and should regularly review them; (b) check the monitoring data provided by operators; and (c) provide evidence that can satisfy the public that authorized sources of exposure are being suitably monitored and controlled."

§ 3.6 (a) states that "although the licensees should be generally responsible for source and environmental monitoring, in some cases (such as major practices or sources) the regulatory body may carry out a limited confirmatory programme of environmental measurements to verify the quality of the results provided by the licensee and to confirm that the doses to members of the public are maintained below the constraints established in the license."

Continuous environmental monitoring for total gamma dose rates is reported for 33 stations on SORNS website. The new instruments deployed at the latest 9 sites were calibrated, however no systematic calibration programme is in place. Samples from environmental compartments are also analyzed by TSOs/laboratories.

SORNS receives monthly monitoring data from NPP Krško. To inform the public, SORNS analyses the data and publish on a quarterly basis information on discharge levels, water temperatures, flow rates and dose exposures to the public for that period.

Calibration of radiation monitoring equipment is required under Annex 4 of Ordinance 121/13, but is not being implemented by SORNS, which is not consistent with Requirement 2 of GSR Par 3 or the guidance specified in RS-G-1.8. As a result, the credibility/reliability of the data used in the decision-making process may be questioned.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The Ordinance 121/13 does not differentiate between types of authorized users or types of monitoring. SORNS also does not enforce operators to carry out monitoring programmes in accordance with its Ordinance. As a result operators have not developed nor implemented monitoring programmes. The existing calibration programme developed by SORNS is not being implemented due to the lack of financial resources. This affects the credibility/reliability of the results that are used in the decision-making process.
(1)	**BASIS: GSR Part 3 Requirement 14, para. 3.37states that** *"The regulatory body shall establish requirements that monitoring and measurements be performed to verify compliance*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	with the requirements for protection and safety. The regulatory body shall be responsible for review and approval of the monitoring and measurement programmes of registrants and licensees."
(2)	**BASIS: GSR Part 3 Requirement 32, states that** *"The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available."*
(3)	**BASIS: RS-G-1.8 para.3.4 states that** *"In relation to the control of discharge practices, the regulatory body has the following general responsibilities:* *(b) Ensuring that the operator complies with the appropriate regulations and regulatory requirements, including those in respect of carrying out such source and environmental monitoring as may be necessary;* *(c) Providing assurance that judgements concerning the safety of the public are based upon valid information and sound methods."*
R34	**Recommendation: SORNS should ensure that monitoring programmes are developed and implemented in accordance with IAEA standards and supported by its regulatory framework.**
S22	**Suggestion: SORNS should consider implementing a calibration programme for all of its monitoring and measuring instruments.**

11.3.3. EXISTING EXPOSURE SITUATIONS, INCLUDING REMEDIATION OF AREAS CONTAMINATED WITH RESIDUAL RADIOACTIVE MATERIAL

Radon

SORNS provides radon maps on their website, with data being collated by TSOs. There are a few areas where indoor radon levels exceed 300 Bq/m^3, some reaching 1500 Bq/m^3. The current reference levels in Croatian legislation for new houses are 200 Bq/m^3 and for existing dwellings at 400 Bq/m^3.

Radon is monitored according to the ordinance for monitoring under Article 18 of the OG 121/13, without mentioning reference levels, but these levels are mentioned in OG 59/13. However, in developing an action plan, SORNS will adopt levels exceeding the reference level of 300 Bq/m^3 set under 2013/59/EURATOM, which also complies with GSR Part 3 Requirement 50. SORNS intends to amend its regulatory framework to support this change in reference level.

The plan is scheduled to be ready by the end of 2015, based on the IAEA draft DS241 on "Protection of the public against indoor exposure to natural sources of radiation to assist national authorities in reducing exposure to radon".

Remediation

Under the national waste strategy, three sites have been identified that are to be remediated: Kutina, Plomin and Kaštel Sućurac. All sites are under the control of the Ministry of Environment.

From a radiological point of view:

- Kutina site has been monitored every two years for at least the last 10 years, but no data forwarded to SORNS. The first report was received two weeks ago. Some results would suggest that levels

are at, or below clearance levels for natural radionuclides, 1 Bq/g, but a proper assessment is required to confirm these levels;

- A previous site at Plomin was successfully remediated, and current monitoring at the other site is being carried out, but no data forwarded to SORNS;
- A previous site at Kaštel Sućurac was successfully remediated. The remaining site has very few radioactive hot spots, but a proper assessment is required to confirm these levels, locations and depths.

Legislation dealing with remediation of areas contaminated with residual radioactive material includes:

- Act on radiological and nuclear safety, 141/13, where Article 63 refers to radioactive substances exceeding the limits set out in the ordinance (53/08);
- Ordinance 53/08 on the ways of removal of radioactive contamination, disposal of radioactive sources, or undertaking other indispensable measures to reduce damage to people and the environment or eliminate further threats is still in force but the IRRS team was informed that it does not cover remediation of sites;
- Ordinance 121/13 on environmental monitoring of radioactivity, where Article 33 gives SORNS power to require monitoring for these sites from the authorized users; and
- the Strategy, OG 125/14, states its obligation to remediate localities where there is NORM that requires continuous regulatory supervision.

The IRRS team noted that there is no remediation process in place for SORNS to discharge its responsibilities according to WS-G-3.1.

Paragraph 2.9 in WS-G-3.1 clearly states that:

> "To discharge its responsibilities as defined in Ref. [4], the regulatory body should have the appropriate resources, including properly trained and experienced staff, facilities and financial commitments. Its responsibilities should include:
>
> a. identifying and quantifying potentially contaminated areas and the associated responsible parties;
> b. prioritizing contaminated areas;
> c. establishing remediation criteria;
> d. specifying the time when remediation activities should be initiated;
> e. reviewing and approving the selected optimized remediation strategy, remediation plans and supporting documents relating to the performance of remediation activities associated with a contaminated site, in terms of radiological, non-radiological and conventional safety;
> f. monitoring the remediation activities during implementation;
> g. verifying that all final conditions have been met prior to terminating regulatory control over the area;
> h. formally terminating regulatory control over the area;
> i. reviewing and approving any restrictions or institutional controls if the area is released for restricted use;
> j. ensuring public participation in all activities associated with the remediation process;
> k. liaising with other regulatory organizations that have responsibilities for non-radiological hazards in the same area."

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Ordinance 53/08 does not address remediation of areas contaminated with residual radioactive material. As a result, no remediation process has been established and no limits and criteria exist to initiate remediation.
(1)	**BASIS: GSR Part 1 Requirement 3, para. 4.29 states that** *"Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas. For radioactive sources and radiation generators, the regulatory process shall continue over their entire lifetime."*
(2)	**BASIS: GSR Part 3 Requirement 47, Responsibilities of the government specific to existing exposure situations, states that** *"The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection."*
(3)	**BASIS: GSR Part 3 Requirement 49, Responsibilities for remediation of areas with residual radioactive material, states that** *"The government shall ensure that provision is made for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; and for putting in place an appropriate strategy for radioactive waste management."*
(4)	**BASIS: WS-G-3.1, para. 3.1 states that** *"The overall remediation process shown in Fig. 1 involves four main activities:* *(a) initial site characterization and selection of remediation criteria;* *(b) identification of remediation options and their optimization, followed by subsequent development and approval of the remediation plan;* *(c) implementation of the remediation plan; and* *(d) post-remediation management."*
R35	**Recommendation: The Government should ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection, in accordance with IAEA standards.**
R36	**Recommendation: SORNS should revise their Ordinances to address the remediation process of areas contaminated with residual radioactive material in accordance with IAEA standards.**

11.4. SUMMARY

11.4.1. CONTROL OF MEDICAL EXPOSURES

With regard to medical exposure, the IRRS team noticed that neither the assessment of the application submitted for authorization nor the inspection process carried out by SORNS cover the full scope of patients' protection. As a result, the protection of patients against undue radiation exposure is not optimal.

Furthermore, there is no specialization in medical physics and insufficient provisions regarding the responsibilities of medical physicists, whereas their contribution in the reduction of patients' doses is essential.

Finally, even if the regulatory framework covers most of requirements of GSR Part 3 related unintended and accidental medical exposures, the process of reporting and investigating them is not effectively implemented neither by licensees nor by SORNS. As a result, the prevention of the recurrence of such accidental medical exposure is not ensured.

11.4.2. OCCUPATIONAL RADIATION PROTECTION

In terms of occupational exposure, the legal and regulatory framework in Croatia is generally consistent with the provisions of GSR Part 3 and the relevant IAEA Radiation Safety Guides. However, some provisions need to be updated or implemented.

In terms of planned exposures dose limits will need to be revised to include the new dose limit for the lens of the eye. In terms of personal dosimetry, arrangements need to be made so that the capability to assess $Hp(0.07)$ and $Hp(3)$ is available to licensees, and with the development of the radwaste management programme the capability to conduct internal dosimetry will also need to be made available. The current regulatory requirements will need to be updated to include the measures to be taken in the event of gaps in the personal dose records of exposed workers and for the general use of calibrated radiation survey meters by licensees.

In existing exposure situations Croatia has developed detailed strategies for dealing with exposure of aircrew to cosmic radiation and for exposure to radon in the workplace. SORNS should consider reviewing and revising its regulatory system for existing exposure situations with a view to implementing only those relevant requirements for occupational exposure of exposed workers.

As part of its national programme of inspections SORNS needs to include routine inspections of the authorized Technical Services Organisations (TSO). As a consequence of the important radiation protection advisory role that TSOs are currently playing in the regulatory process in Croatia, the process for authorizing TSOs and the requirements for authorization should be expanded to incorporate a requirement for TSOs to demonstrate competence as a recognized Qualified Expert consistent with the IAEA Safety Standards. Such a development will entail TSOs undergoing significantly more detailed training in radiation protection.

Currently, SORNS does not have the required staff with the required level of expertise to assess the work of the TSOs and licensees particularly in relation to radiation protection, Quality Assurance, Risk Assessments, TSO Opinions and Personal Dosimetry.

11.4.3. CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

With regards to liquid and gaseous radioactive discharges, SORNS should ensure optimization of protection and safety is achieved and discharge limits imposed on licences in accordance with WS-G-2.3.

Monitoring programmes by licensees should be implemented and enforced by SORNS in accordance with RS-G-18. Any monitoring data being assessed should be supported by calibration, so SORNS should ensure that arrangements are in place for the provision of calibration of monitoring and measuring equipment.

SORNS should discharge its responsibilities with regard to remediating areas contaminated with residual radioactive material in accordance with the remediation process described in WS-G-3.1.

12. POLICY ISSUES

1. Implementation of the Strategy for Management of Radioactive Waste, Disused Sources and Spent Fuel in the Republic of Croatia

Director General of SORNS presented the current situation in the area of radioactive waste, disused sources and spent nuclear fuel management and the systematic approach to solving the problem. This approach is established in the Strategy for the Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel (Strategy). The Strategy has been developed in accordance with requirements given in the Bilateral Agreement between the Government of the Republic of Croatia and the Government of the Republic of Slovenia on the settlement of the status and other legal relations with respect to investments, utilization of and decommissioning of the Krško Nuclear Power Plant (NPP). International standards and best practices were taken into account when developing the Strategy.

The Strategy is based on the current inventory; future generation of disused sources and radioactive waste; transfer of operational waste from the Krško NPP, decommissioning waste and spent fuel. It also covers remediation of sites that contain naturally occurring radioactive materials as well as in the field of radioactive waste and spent fuel management. The Strategy highlights the importance of the need for the development, construction and operation of the Central National Storage Facility for radioactive waste and disused sources generated in the country.

The major strategic goals are distributed into short-term goals (2 years), medium-term goals (10 years) and long term goals (more than 10 years). These goals are broadly defined and elaborated for the each particular field of application. In order to fulfil the goals, the Strategy sets out general guidelines regarding the legislative framework, responsibilities, funding, human resources and public participation.

The short-term strategic goals were the main focus of this discussion.

Background information:

There are two storage facilities for radioactive waste in Croatia. These are located at the Institute for Medical Research and Occupational Health (IMROH) and the Institute Rudjer Boskovic (IRB). The radioactive waste and disused sources stored at these facilities originated from medical applications, industrial applications, scientific and educational applications and from the past public use of (lightning rods and smoke detectors.

The IMROH storage facility operated from 1995 up to 2000 when it was closed. Remediation work on the stored materials assuming segregation, characterization, conditioning and packing into lead containers was undertaken in June 2006 with the full assistance of the IAEA. The work was performed under the supervision of the former State Office for Radiation Protection and the conditioned waste and disused sources are stored at the IMROH facility pending transfer to the future Central National Storage Facility.

The IRB storage facility was built in 1967 for the purpose of storing radioactive waste and disused sources generated within the IRB. Over time, e storage facility has been used for storing radioactive waste and disused sources that were generated outside the IR As a result of storage capacity and regulatory issues the IRB storage facility was closed and a remediation project that assumes segregation, characterization, treatment, conditioning and packing of radioactive waste and disused sources was launched. After completion of the remediation project, the conditioned waste and disused sources will be transported and stored in the future Central National Storage Facility too.

According to the Strategy, the Central National Storage Facility is to be developed, constructed and operational within two years from now. The development of a basic design of the facility and preliminary safety assessment is under way with the support of an independent expert.

The National Programme that implements the Strategy has been drafted and in these discussions the IRRS team encouraged the responsible authorities in Croatia (Radioactive Waste Management Agency and SORNS) to finalize, approve and implement the Programme.

The IRRS team advised SORNS to devote specific attention to such future challenges as:

- exercising their regulatory role in relation to radioactive waste management;
- evaluation of the preselected site future disposal of radioactive waste and a need of for new safety assessment;
- development of the safety analysis and public communication expertise in the country and involvement of the international experts;
- development of a comprehensive set of regulations and guides for radioactive waste disposal;
- development of waste acceptance criteria for the future disposal facility.

2. Policy issue on revision of emergency planning zones in the Republic of Croatia

The policy issue was introduced by Mr Davor Rašeta, who gave a presentation on the revision of urgent protective action planning zone (UPZ) established in 1999 on the Croatian territory in relation to the Krsko NPP located in Slovenia and the on-going efforts of SORNS and its Slovenian counterpart to harmonize the emergency planning zones and response strategies at the both sides of the border.

Namely, the Slovenian NPP Krsko is located at 11 km from the Croatian border. Thus, the area where urgent protective actions may be warranted in a case of a nuclear accident expands on the territory of Croatia too. Currently, UPZ in Slovenia is at 10 km, while Croatia has UPZ at 25 km from the Krsko NPP. Slovenian counterpart has initiated a dialog with SORNS in 2013 with the aim to harmonize the emergency planning zones and response strategies at the both sides of the border taking into account IAEA Safety Standards and technical guidance, new WENRA-HERCA approach for planning for severe emergencies and the safety improvements made in NPP Krsko. This dialogue resulted in both sides agreeing a harmonized response strategy on the both sides of the border in relation to prompt and direct notification of an emergency from NPP Krsko to national warning point (112 service) in Croatia and long-term protective actions up to 100 km around the NPP Krsko. However, the issue of harmonizing the size of and the response strategy within UPZ remained open.

SORNS looked for an advice by the IRRS team members on further steps in determining the exact size of UPZ and in harmonizing the response strategy with Slovenia within UPZ.

IRRS team welcomed the current achievement in coordination and harmonization of EPR among both States and encouraged SORNS to continue the dialogue with Slovenia to harmonize remaining issue. To facilitate this, the IRRS team advised SORNS to extend the collaboration with Slovenia at a technical level, e.g. carrying out joint exercises, as this may help both sides to better understand each other's needs and capability in EPR and to build trust. SORNS staff benefitted from the experience of harmonization of zone sizes and response strategies between Bulgaria and Romania and their collaboration in EPR in relation to Kozloduy NPP.

The IRRS team and SORNS staff discussed the importance of consideration of national circumstances (e.g. population and area affected, resources available to implement protective actions, national criteria for implementing protective actions etc.) in addition to NPP safety analysis when ensuring that the response strategies are justified and optimized within UPZ, as described in IAEA Safety Standards and technical tools.

IRRS team highlighted the importance for Croatia now to develop detailed arrangements to implement already agreed strategy with Slovenia. Continuing the discussions on harmonization to be achieved within UPZ should not prevent Croatia to prepare to deal with a nuclear accident at any time.

APPENDIX 1 LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS			
1.	**MAKAROVSKA** Olga	Counsellor of the State Nuclear Regulatory Inspectorate Chairman of Ukraine	Makarovska@hq.snrc.gov.ua
2	**BOSNJAK** Jovica	State Regulatory Agency for Radiation and Nuclear Safety Bosnia and Herzegovina	jovica.bosnjak@darns.gov.ba
3.	**DUSIC** Darja Slokan	Slovenian Nuclear Safety Administration (SNSA) Slovenia	Darja.Slokan-Dusic@gov.si
4.	**LANRIVAIN** Isabelle	Autorité de sûreté nucléaire (ASN) France	Isabelle.LANRIVAIN@asn.fr
5.	**ŠKRABAN** Aleš	Slovenian Nuclear Safety Administration (SNSA) Slovenia	ales.skraban@gov.si
6.	**STATKUS** Vaidas	Radiation Protection Centre Lithuania	vaidas.statkus@rsc.lt
7.	**MADDEN** Jack	Environmental Protection Agency Ireland	j.madden@epa.ie
8.	**NIZAMSKA** Marina	Bulgarian Nuclear Regulatory Agency (BNRA) Bulgaria	M.Nizamska@bnra.bg
9.	**PAŠKOVÁ** Zuzana	State Office for Nuclear Safety Czech Republic	zuzana.paskova@sujb.cz
10.	**ZINGER** Irene	Senior Expert Australia	us.kingsford@gmail.com
IAEA STAFF MEMBERS			
1.	**DJERMOUNI** Belkacem	Division of Radiation, Transport and Waste Safety	B.Djermouni@iaea.org
2.	**PACHECO** Ronald	Division of Radiation, Transport and Waste Safety	R.Pacheco.jimenez@iaea.org

INTERNATIONAL EXPERTS			
3.	**NESTOROSKA MADJUNAROVA** Svetlana	Incident and Emergency Centre	S.Nestoroska-Madjunarova@iaea.org
4.	**SWOBODA** Zumi	Division of Radiation, Transport and Waste Safety	Z.Swoboda@iaea.org
LIAISON OFFICER			
1.	**POPOVIĆ** Stela	Liaison Officer	stela.popovic@dzrns.hr

APPENDIX 11 LIST OF COUNTERPARTS

IRRS EXPERTS	COUNTERPART
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	
Olga Makarovska Aleš Škraban	Nevenka Novosel
GLOBAL SAFETY REGIME	
Olga Makarovska Aleš Škraban	Nevenka Novosel
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	
Olga Makarovska Aleš Škraban	Nevenka Novosel
MANAGEMENT SYSTEM	
Darja Slokan Dusic	Sunčana Podhraški Benković
AUTHORIZATION	
Jovica Bosnjak Ronald Pacheco Zuzana Pašková Vaidas **S**tatkus	Ivana Kralik
REVIEW AND ASSESSMENT	
Jovica Bosnjak Ronald Pacheco Zuzana Pašková Vaidas **S**tatkus	Ivana Kralik
INSPECTION	
Jovica Bosnjak Ronald Pacheco Zuzana Pašková Vaidas **S**tatkus	Renata Laknar Željka Topolovac
ENFORCEMENT	
Jovica Bosnjak Ronald Pacheco	Renata Laknar Željka Topolovac

IRRS EXPERTS	COUNTERPART
Zuzana Pašková Vaidas **S**tatkus	
REGULATIONS AND GUIDES	
Jovica Bosnjak Ronald Pacheco Zuzana Pašková Vaidas **S**tatkus	Nevenka Novosel Ivana Kralik Boris Ilijaš
EMERGENCY PREPAREDESS AND RESPONSE	
Marina Nizamska Svetlana Nestoroska Madjunarova	Davor Rašeta
ADDITIONAL AREAS - Medical Exposure	
Isabelle Lanrivain	Ivana Kralik
ADDITIONAL AREAS - Occupational Exposure	
Jack Madden	Zdravka Tečić
ADDITIONAL AREAS - Control of radioactive discharges and materials for clearance, Environmental monitoring associated with authorized practices for public radiation protection purposes Control of chronic exposures	
Irene Zinger	Sanja Krča

APPENDIX III MISSION PROGRAMME

<table>
<tr><th>Time</th><th>SAT 6</th><th>SUN 7</th><th>MON 8</th><th>TUE 9</th><th colspan="2">WED 10</th><th colspan="3">THURS 11</th><th>FRI 12</th><th>SAT 13</th><th>SUN 14</th></tr>
<tr><td>8:00-10:00</td><td rowspan="8">Arrival of Team Members</td><td rowspan="2"></td><td rowspan="2">Entrance Meeting</td><td rowspan="2">Parallel Group Interviews</td><td rowspan="2">Parallel Group Interviews</td><td rowspan="2">Site Visits
1.Medical(Jovca and Isabelle)
2. Industrial facility (Jack and Vaidas)
3.Radioactive Storage in nuclear medicine facility (Zuzana and Irene)</td><td rowspan="3">Parallel Group Interviews</td><td rowspan="3">TC writes introductory parts</td><td rowspan="3">Site visits Dosimetry Service (Jack)</td><td rowspan="3">TM write Report
TL review introductory part</td><td rowspan="3">• Discussing and improving Draft Report
• Cross-Reading Team</td><td rowspan="3">Cross-Reading TL, TC and TMs-editors read everything finalization</td></tr>
<tr><td>10:00-11:00</td></tr>
<tr><td>11:00-12:00</td></tr>
<tr><td>12:00-13:00</td><td rowspan="2">Lunch</td><td rowspan="2">Lunch</td><td rowspan="2">Standing lunch</td><td rowspan="2">Standing lunch</td><td rowspan="2">Standing lunch</td><td rowspan="2">Standing lunch</td><td rowspan="2">Standing lunch</td><td rowspan="6">By 12:00- Submission of the Draft to SORNS</td></tr>
<tr><td>13:00-14:00</td></tr>
<tr><td>14:00-15:00</td><td rowspan="3">Initial Team Meeting:
• IRRS process
• Main objectives
• Report writing
• Schedule
• First observations
• In-Group discussions</td><td rowspan="3">Parallel Group Interviews</td><td rowspan="3">Parallel Group Interviews
13:00 Deputy Head of office of Prime Minister
14:00Deputy Minister of Health
15:00 Deputy DG of National Protection and Rescue Directorate
16:00 DG SORNS</td><td rowspan="2">Parallel Group Interviews/findings preparation</td><td rowspan="2">Findings preparation</td><td rowspan="2">Policy Issues Discussion session</td><td rowspan="3">TM write Report/ Follow-up Interviews</td><td rowspan="3">Finalization of the Draft Report</td></tr>
<tr><td>15:00-16:00</td></tr>
<tr><td>16:00-17:00</td><td colspan="2">Written preliminary findings delivered to TL</td><td rowspan="2">Daily Team Meeting/Findings discussion</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting</td><td>Daily Team Meeting</td><td colspan="2" rowspan="2">Daily Team Meeting/ Findings discussion</td><td>Draft text of report delivered to TL</td></tr>
<tr><td>18:00-22:00</td><td></td><td>Team Dinner</td><td>Dinner/writing of report</td><td>Dinner and writing of report</td><td>Dinner and writing of report</td><td>Dinner and TM read draft report</td><td>Dinner and TL,TC edits report</td></tr>
</table>

<table>
<tr><th></th><th>MON 15</th><th>TUES 16</th><th>WED 17</th></tr>
<tr><td>8:00-12:00</td><td>TC prepares Executive Summary and exit presentation</td><td>Submission of the final draft report</td><td rowspan="2">Social Event</td></tr>
<tr><td>12:00-13:00</td><td>Lunch</td><td>Lunch</td></tr>
<tr><td>13:00-15:00</td><td rowspan="3">Written comments on draft provided by SORNS
General discussions with team</td><td></td><td rowspan="4">Departure Home</td></tr>
<tr><td>15:00-17:00</td><td rowspan="2">Exit meeting</td></tr>
<tr><td>17:00-18:00</td></tr>
<tr><td>18:00-20:00</td><td>Dinner</td><td>Dinner</td></tr>
</table>

APPENDIX IV SITE VISITS

1. Hospital: KBC Sestre milosrdnice (University Hospital Center“ Sisters of Charity)
2. Industrial facility: ZIT d.o.o. (ZIT ltd. – Office for Welding, Testing and Technology)
3. Dosimetry Service: IMI (Institute for Medical Research and Occupational Health (IMROH))

APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**	R1	The Government should establish a national policy and strategy for safety in accordance with Requirement 1 of GSR Part 1.
		R2	The Government should complement the framework for safety with: provisions for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively; provisions related to a graded approach; provisions on criteria for release from regulatory control; provision that stipulates that compliance with regulations does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.
		R3	The Government should provide SORNS with human and financial resources enabling SORNS to completely fulfil its statutory obligations for regulatory control.
		S1	The Government should consider organizing training and refresher courses in a way that do not compromise effective independence of SORNS.
		R4	The Government should implement the provisions for the safe management of radioactive waste in particular with the construction and operation of the Central National Storage Facility in compliance with the Strategy for the Management of Radioactive Waste, Disused Sources and Spent Nuclear Fuel.
2.	**GLOBAL SAFETY REGIME**	R5	SORNS should established and maintain process and procedures for analysing and disseminating the lessons learned from national and international operating experience and regulatory experience to be used by SORNS, other authorities and authorized parties.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	R6	SORNS should have sufficient resources and optimize them in order to discharge its responsibilities and perform its functions in a manner commensurate with the radiation risks associated with facilities and activities.
		R7	SORNS should prepare and implement comprehensive training plans in order to improve knowledge, skills and abilities to perform all the functions and responsibilities.
		S2	SORNS should consider performing systematic periodic screening/review of radiological and nuclear safety legislation, to ensure keeping regulatory safety requirements complete and up-to-date.
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	R8	SORNS should appoint an individual with the authority to coordinate and develop the integrated management system and to raise issues relating to the management system to the senior management.
		R9	SORNS should develop an integrated management system in line with IAEA safety standard GS-R-3.
		S3	SORNS should consider revising its strategic plan to expand the requirements on management system from the quality assurance programme to the integrated management system.
		S4	SORNS should consider preparing the plan for establishment, development, and implementation of an integrated management system where the priorities are stressed out such as defining responsibilities for the management system, defining key processes related to inspection, licensing, etc. and defining the interactions among the processes.
5.	**AUTHORIZATION**	R10	The Government should establish a regulatory system for protection and

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			safety that includes notification process, with criteria for when notification only is sufficient.
		S5	SORNS should consider developing a system of authorization commensurate with the radiation risks associated with the facility or activity taking into account a graded approach.
		R11	SORNS should develop and approve Ordinance regarding the detailed requirements for licensing the site, construction, operation and closure radioactive waste management facility as prescribed in the 2013 Act.
6.	**REVIEW AND ASSESSMENT**	R12	SORNS should establish process and procedures governing the review and assessment activities for all types of facilities and activities under their regulatory control, taking into account graded approach.
		S6	SORNS should consider introducing pre-licensing verification of the contents of the documents submitted for review and assessment of an application for authorization to confirm credibility of submitted documents, where appropriate.
7.	**INSPECTION**	R13	SORNS should establish inspection programme that commensurate with the radiation risks associated with the facility or activity in accordance with a graded approach that covers all areas relevant to safety and radiation protection and implement this programme.
		R14	The Government should empower SORNS inspectors to carry out announced inspections.
		R15	SORNS should review the draft "Manual for conducting inspection supervision" to cover all elements of inspections and approve it.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S7	SORNS should review its inspection programme and include tests and measurements as a method of inspection.
8.	**ENFORCEMENT**	R16	SORNS should establish detail procedures for determining and exercising enforcement actions. All inspectors and other staff of SORNS should be trained in, and knowledgeable about, the procedures.
		S8	SORNS should consider providing inspectors with legal support to carry out enforcement actions.
9.	**REGULATION AND GUIDES**	S9	SORNS should consider developing guides to help users striving to achieve the high levels of safety.
		S10	SORNS should establish within its regulatory framework processes and procedures for reviewing and revising regulations, taken into account internationally agreed standards and the feedback of relevant experience.
		S11	SORNS should consider reviewing its ordinances for compliance with GSR Part 3.
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R17	SORNS should revise and strengthen its regulatory framework in EPR consistently with IAEA Safety Standards to also include inspection, enforcement and evaluation of some of operator's exercises and should implement a graded approach.
		R18	SORNS should require that operators develop and implement a system for classifying all potential nuclear or radiological emergencies and for activation of an adequate level of emergency response consistently with IAEA Safety Standards.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S12	SORNS should consider setting response time objectives for notification of an emergency and for activation of an emergency response.
		R19	The Government should review and revise the responsibility of SORNS to manage the on-site emergency response, to implement urgent protective actions on-site in relation to facilities and activities under the responsibility of an operator and, in this regard, to provide public information as a single source.
		R20	SORNS shall require operators to implement clear command and control system to manage effectively the on-site emergency response.
		S13	SORNS should consider requesting that operators establish formal arrangements or protocols with off-site emergency services providing the operator with an assistance and support during the on-site emergency response.
		S14	SORNS should consider continuing its efforts to coordinate and harmonize emergency planning zones with their Slovenian counterparts in relation to Krsko NPP in line with relevant IAEA Safety Standards.
		S15	SORNS should consider updating the intervention levels and generic action levels for taking protective actions set forth in Ordinance 59/13 taking account of the latest IAEA Safety Standards.
		R21	SORNS should develop a regulatory guide to facilitate systematic development of on-site emergency arrangements by operators and an internal process to facilitate its systematic review and assessment of the operator’s emergency plan and programme.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R22	SORNS should develop its own emergency arrangements consistently with IAEA Safety Standards to fulfill its roles in emergency response.
		S16	The Government should consider reviewing and revising the roles and responsibilities assigned to SORNS in emergency response in order to avoid compromising SORNS regulatory responsibilities and taking into account IAEA Safety Standards as well as the responsibilities of other State bodies and organizations.
11.1	**CONTROL OF MEDICAL EXPOSURES**	R23	SORNS, in coordination with The Ministry of Health, should initiate arrangements for assigning responsibilities for justification. SORNS should also ensure that only justified practices are authorized.
		R24	The Ministry of Health and SORNS should issue the necessary guidelines, in cooperation with the relevant professional and scientific bodies, in accordance with the requirement of GSR Part 3.
		R25	The Government should recognize medical physicists as a profession at a national level and develop specialization in medical physics with objective to ensure the radiation protection of patients.
		R26	SORNS should review its regulation to supplement the responsibilities of medical physicists so that they are fully integrated in all medical practices in accordance with GSR Part 3.
		S17	: SORNS should consider making provisions for informing carers, comforters and patients, in particular breast feeding women, about the radiation risks, in accordance with GSR Part 3.
		R27	SORNS should ensure that the existing requirements for optimization are

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			fully implemented in all medical practices and that requirements regarding responsibilities of medical physicists, quality assurance, quality control and calibration are in accordance with the IAEA standards.
		R28	SORNS should ensure that the existing requirements for reviews and records related to medical exposure are implemented in all medical practices and supplement its Ordinances to improve assessment and recording of patient doses in accordance with GSR Part 3.
		R29	SORNS should ensure that all requirements related to unintended and accidental medical exposure are implemented in compliance with the requirement of GSR Part 3.
		S18	Since SORNS has not received any unintended or accidental exposure reports to date, SORNS should consider supporting this notification process through developing guidelines or/and training of medical staff and medical physicists.
11.2	**OCCUPTIONAL RADIATION PROTECTION**	R30	SORNS should put in place a programme of inspection of authorized TSOs as part of their annual inspection programme to establish that all authorized TSOs are maintaining the prescribed requirements of their authorizations.
		R31	SORNS should initiate in consultation with the relevant government departments and state agencies the development of a formal recognition for qualified experts and an additional requirement for TSOs to have a qualified expert on their staff should be included in SORNS process for authorizing TSOs.
		R32	The Government should define the concept of an emergency worker taking into account the IAEA safety standards and should establish a programme for managing, controlling and recording the doses received in an emergency

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			by emergency workers. This programme should be implemented by response organisations, licensees and SORNS.
		S19	SORNS should consider reviewing and revising its regulatory system for existing exposure situations with a view to implementing only those relevant requirements for occupational exposure of exposed workers.
		S20	SORNS should consider revising Article 23 (3) of the Ordinance on Measurement of Personal Doses, Examination of Ionizing Radiation Sources and Working Conditions and on Reports and Registers (OG 41/12) in accordance with IAEA Safety Guide RS-G-1.3 Section 8.
		S21	SORNS, in light of the introduction of the new dose limit for the lens of the eye and the development of the radwaste management programme, should consider introducing arrangements so that a national capability for extremity dose assessment *Hp*(0.07) and *Hp*(3) together with a national capability for internal dosimetry is available. The relevant ordinance on Measurement of Personal Doses, Examination of Ionizing Radiation Sources and Working Conditions and on Reports and Registers (OG 41/12) should be revised in accordance with IAEA Safety Guides.
11.3	**CONTROL OF RADIOACTIVE DISCHARGES AND MATERIAL FOR CLEARANCE, ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES** **CONTROL OF CHRONIC EXPOSURES**	R33	SORNS should review their regulatory framework with regards to liquid and gaseous radioactive discharges and ensure the optimization of protection and safety is achieved and discharge limits imposed on licences that cover such discharges.
		R34	SORNS should ensure that monitoring programmes are developed and implemented in accordance with IAEA standards and supported by its regulatory framework.
		S22	SORNS should consider implementing a calibration programme for all of

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			its monitoring and measuring instruments.
		R35	The Government should ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection, in accordance with IAEA standards.
		R36	SORNS should revise their Ordinances to address the remediation process of areas contaminated with residual radioactive material in accordance with IAEA standards.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

1.	01a_Regulation on environmental impact assessment OG 64-08.pdf
2.	01b_Regulation on amendments to the Regulation on environmental impact assessment OG 67-09.pdf
3.	03_Ordinance on the authorisation of expert technical services OG 72-11.doc
4.	03_Regulation on strategic environmental assessment of plans and programmes OG 64-08.pdf
5.	Act on administrative disputes OG 20-10.doc
6.	Act on administrative disputes OG 20-10.doc
7.	Act on Amendments to the Occupational Health and Safety Act OG 75-09
8.	Act on Amendments to the Occupational Health and Safety Act OG 75-09.pdf
9.	Act on Amendments to the Personal Data Protection Act 118-06
10.	Act on Amendments to the Personal Data Protection Act 118-06.pdf
11.	Act on amendments to the waste act OG 111-06.doc
12.	Act on general use items OG 39-13.doc
13.	Act on general use items OG 39-13.doc
14.	Act on ionising radiation protection and safety of ionising radiation sources OG 64-06.doc
15.	Act on liability for nuclear damage NN 143-98.doc
16.	Act on nuclear safety OG 173-03.doc
17.	Act on State Administration System 190-03 NE VAŽI.pdf
18.	Act on Sustainable Waste Management OG 94-13.pdf
19.	Act on the prevention of conflict of interest (163-03 - 60-80) NE VAŽI.pdf
20.	Addendum to ARM.docx
21.	Amendments of the law on accreditation 75-09
22.	Amendments to the degree on the foundation charter of the accreditation agency 30-2010
23.	Amendments to the degree on the foundation charter of the accreditation agency 44-05
24.	Civil service act OG 92-05.doc
25.	Code of Ethics for Civil Servants OG 40-11
26.	Code of Ethics for Civil Servants OG 40-11 to 27-08
27.	Code of Ethics for Civil Servants OG 40-11.pdf
28.	Code of Practive on consultation OG-140-09
29.	Commission Regulation (Euratom) No 302-2005.pdf
30.	Commission Regulation (Euratom) No 66-2006.pdf
31.	Constituation of the Republic of Croatia
32.	Council Directive 2006-117-Euratom.pdf

33.	Council Directive 2009-71-Euratom.pdf
34.	Council Directive 2013-59-Euratom.pdf
35.	Council Regulation (Euratom) No 1493-93.pdf
36.	Country Programme Framework 2014 – 2019 Part 1
37.	Country Programme Framework 2014 – 2019 Part 1
38.	CPF 2014-2019 Part 1.pdf
39.	CPF 2014-2019 Part 2.pdf
40.	Criminal Procedure Act OG 62-03 NE VAŽI.doc
41.	Croatian legislation in the field of radiological and nuclear safety.docx
42.	Croatian_Act_on_Personal_Data_Protection 103-03.pdf
43.	Croation Act on Personal Data Protection 103-03
44.	Data Secrecy Act OG-79-07
45.	Decree on the foundation charter of the Croatian accreditation agency nn 158-04
46.	Energy act OG 120-12 (UNOFFICIAL TRANSLATION).pdf
47.	Energy Act OG-120-12
48.	Energy strategy of the Republic of Croatia OG 130-09.doc
49.	Environmental Protection Act OG 110-07.pdf
50.	Environmental Protection Act OG 80-13.pdf
51.	Final Report 2011 V1.pdf
52.	Final Report 2013_v2.docx
53.	General administrative procedure act OG 47-09.doc
54.	Information Security Act OG 79-07
55.	IRRS SARIS Report Croatia Final.pdf
56.	IRRS and SARIS Croatian reports notes.docx
57.	LABOUR ACT OG 137-04 NE VAŽI.pdf
58.	Law on accreditation 158-03
59.	Ordinance on conditions for nuclear safety and protection OG 71-08.doc
60.	Ordinance on the method of removal of radioactive contamination OG 53-08.doc
61.	Ordinance on the requirements for the design, construction and removal OG 99 08.doc
62.	Personal Data Protection Act OG 106-12.doc
63.	Regulation on the amounts, time limits and method of payment of resources OG 155 08.doc
64.	Regulations on classified information marking the content and form of security clearance and the statement OG-102-07
65.	SAFETY AND HEALTH PROTECTION AT THE WORKPLACE ACT, 1996.doc
66.	SARIS CROATIA Final Report 2014-2015.pdf
67.	SARIS Abbreviations Croatia.docx

68.	Security Vetting Act OG-85-08
69.	Strategy of Waste Management in the Republic of Croatia OG 130-205.pdf
70.	The criminal act OG 125-11.doc
71.	The dangerous goods transport act OG 79-07.pdf
72.	The law on the right of access to information OG 25-13.doc
73.	Waste act OG 178-04.doc
74.	WASTE MANAGEMENT PLAN (OG 85-07,126-10, 31-11).pdf
75.	Waste management plan in the Republic of Croatia for the period from 2007. - 2015. OG 85-07.pdf

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. INTERNATIONAL ATOMIC ENERGY AGENCY - No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1 (Vienna2010)
3. INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for a Nuclear and Radiological Emergency Safety Requirement Series No. GS-R-2 IAEA Vienna (2002)
4. INTERNATIONAL ATOMIC ENERGY AGENCY The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3 IAEA, Vienna (2006)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, 2014 edition
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities Using Radioactive Material Safety, Safety Requirement Series No. WS-R-5, IAEA, Vienna (2006)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
13. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
14. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)
15. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
16. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
17. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)
18. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
19. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)
20. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)
21. 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 ORGANIZATION CHART