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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

SWITZERLAND

Brugg, Switzerland

18 to 29 October 2021

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

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Integrated Regulatory Review Service

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

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IAEA IRRS

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

Mission dates:	*18 to 29 October 2021*
Regulatory body visited:	*Swiss Federal Nuclear Safety Inspectorate (ENSI)*
Location:	*ENSI HQ in Brugg, Switzerland*
Regulated facilities, activities, and exposure situations in the mission scope:	*Nuclear power plants, research reactors, waste management and storage facilities, emergency preparedness and response, transport, decommissioning, occupational exposure control, environmental monitoring, control of discharges and public exposure, interfaces with nuclear security*
Organized by:	*International Atomic Energy Agency (IAEA)*

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IAEA-2021

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 Switzerland, an international team of senior safety experts met representatives of the Swiss Federal Nuclear Safety Inspectorate (ENSI), from 18 to 29 October 2021 to conduct an Integrated Regulatory Review Service (IRRS) mission as part of its second IRRS cycle as recommended by the IRRS guidelines. The review took place at the headquarters of ENSI in Brugg AG.

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

The IRRS team consisted of 17 senior regulatory experts from 15 IAEA Member States, 2 IAEA staff members and 1 IAEA administrative assistant. The IRRS team reviewed the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities and processes of the regulatory body including authorization, review and assessment, inspection, enforcement, development and content of regulations and guides, emergency preparedness and response. The review also included the optional review area on interface with nuclear security. Facilities, activities and exposure situations covered all those regulated by ENSI including nuclear power plants, a research reactor, radiation source applications in nuclear facilities, waste management facilities, decommissioning, transport of radioactive material, occupational and public exposure in nuclear facilities. Medical exposure was out of scope. Existing exposure situations were out of scope except for specific situations that were encountered in nuclear facilities (mainly radon exposure at workplaces). The IRRS mission included discussion of two policy issues: Counterfeit, Fraudulent, and Suspect Items (CFSI); and Regulatory Implications of Pandemic Situations.

The IRRS team conducted interviews and discussions with the staff of ENSI. Members of the IRRS team also observed regulatory activities at an operating nuclear power plant and at a nuclear power plant under decommissioning, a research reactor, and radioactive waste management facilities. The visits included discussions with management and staff of facilities. Meetings with the Federal Department of the Environment, Transport, Energy and Communications (DETEC), the ENSI Board, the Swiss Federal Department of Foreign Affairs (FDFA), the Swiss Federal Office of Energy (SFOE), the Swiss Federal Office of Public Health (FOPH), the Swiss Federal Office of Civil Protection (FOCP), the Swiss Nuclear Safety Commission (NSC), the Swiss Accident Insurance Fund (SUVA), the Swiss National Cooperative for the Disposal of Radioactive Waste (NAGRA), representatives from the Leibstadt Nuclear Power Plant and the Gösgen Nuclear Power Plant, as well as members from the NGO “Swiss Energy Foundation” were also organized.

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

The IRRS team acknowledged the outstanding efforts of the participating authorities, including ENSI, to engage in this extensive international peer review. The participation by the above organisations enabled the IRRS team to develop a broad understanding of the regulatory framework resulting in recommendations and suggestions that should benefit nuclear and radiation safety for all in Switzerland.

Switzerland has a comprehensive and robust regulatory framework for nuclear and radiation safety covering facilities and activities regulated by ENSI. ENSI is considered a mature and competent regulator with a high level of independence which ensures it is able to fulfil its statutory obligations without undue influence.

The IRRS team identified two good practices in the area of safety culture. ENSI has continuously developed and improved its internal safety culture. In addition, ENSI promotes safety culture of licensees through holding periodic dialogues in format of focus groups with the senior leadership teams and safety culture specialists of the NPP licensees. These are considered an effective tool for proactively engaging senior management of NPP operators to promote self-awareness of their impact as leaders on the safety culture of their organizations.

The IRRS team also identified a number of areas of good performance evidenced by the policies, the regulatory framework, as well as the regulatory and operational activities implemented by the Swiss authorities, including:

- Role of ENSI to implement the regulatory policy and the associated requirements for continued safety improvement at nuclear power plants;

- Anticipated dialogue and collaboration among all Federal and Cantonal authorities involved in the licensing process of nuclear facilities;
- The periodic personal security background tests for ENSI's staff, including evaluation of possible lack of impartiality.

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

The IRRS team considers that the main challenge in Switzerland is maintaining and building competence of the parties that have responsibilities for safety, particularly in the Swiss context of phasing out nuclear power. Switzerland needs to build and maintain expertise in the mid- and long-term perspective to ensure continued safety of the operating nuclear facilities, decommissioning of nuclear facilities and safety of final disposal for radioactive waste. The Government of Switzerland should evaluate the expertise needs and establish actions to fulfil them.

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

Government

- to set up legal provisions that also allow prosecution of a licensee instead of an individual;
- to establish a binding obligation for the authorized parties to inform the public about safety relevant occurrences associated with the operation of their facilities;
- to ensure that all nuclear facilities will be subject to periodic safety reviews in accordance with a graded approach.

ENSI

- to update its enforcement procedures for clarifying the role of inspectors in the enforcement process, including in relation to immediate corrective actions inspectors are authorized to take.

Additionally, the IRRS team identified areas for improvement in ENSI's inspection processes, in keeping regulatory guides updated and in line with the IAEA Safety Standards, and in the management system.

The IRRS team highlighted the extended full support and cooperation in the regulatory, technical, and policy issues by all parties in a very open, transparent and frank manner, throughout the mission.

This IRRS initial mission was conducted as part of the second IRRS cycle of Switzerland. Inviting international peer reviews is considered a sign of openness, transparency and commitment to continuous improvement. However, like in previous missions, this mission had a reduced scope since the Swiss regulatory infrastructure for safety of radiation facilities and activities has not been included. Switzerland is encouraged to invite an IRRS follow up mission with an extended scope in order to review the areas not covered by this mission.

I. INTRODUCTION

At the request of the Government of Switzerland, an international team of senior safety experts met representatives of the Swiss Federal Nuclear Safety Inspectorate (ENSI), from 18 to 29 October 2021 to conduct an Integrated Regulatory Review Service (IRRS) mission. The review mission was formally requested by the Government of Switzerland in April 2019. It took place at the headquarters of ENSI in Brugg AG.

The purpose of this mission was to review the Swiss governmental, legal and regulatory framework for nuclear and radiation safety within the competence of ENSI. Therefore, the mission did not include a comprehensive review of the national regulatory infrastructure for radiation safety of Switzerland.

A preparatory meeting was conducted virtually from 3 to 4 March 2021 to discuss the purpose, objectives and detailed preparations of the review in connection with facilities and activities regulated by ENSI and their related safety aspects and to agree upon the scope of the IRRS mission.

The IRRS team consisted of 17 senior regulatory experts from 15 IAEA Member States, two IAEA staff members and one IAEA Administrative Assistant. The IRRS team was led by Mr. Petteri Tiippana from Finland who was assisted by Ms. Isabel Villanueva from Spain as the Deputy Team Leader, and coordinated by Mr Jean-René Jubin as the IAEA Team Coordinator, and Mr Jovica Bosnjak as the Deputy Team Coordinator. The IRRS team reviewed the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities and processes of the regulatory body including authorization, review and assessment, inspection, enforcement, development and content of regulations and guides, emergency preparedness and response. The review included also the optional review area on interfaces with nuclear security. Facilities, activities and exposure situations within ENSI's oversight included nuclear power plants, a research reactor, radiation source applications in nuclear facilities, waste management facilities, decommissioning, transport of radioactive material, planned occupational and public exposure situations for nuclear facilities. Existing exposure situations were out of scope except for specific situations that were encountered in nuclear facilities (mainly radon exposure at workplaces). Medical exposure was out of scope. The IRRS mission was also used to evaluate and discuss the national regulatory implications of the COVID-19 pandemic in Switzerland. In addition, two policy issues were discussed: Regulatory Implications of Pandemic Situations; and Lessons Learned and International Developments related to the Management of Counterfeit, Fraudulent, and Suspect Items (CFSI).

ENSI conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of ENSI's self-assessment and supporting documentation were provided to the IRRS team as Advance Reference Material (ARM) for the mission in August 2021. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the Swiss ARM, conduct of interviews with management and staff from ENSI and direct observation of ENSI oversight activities at regulated facilities. Meetings with the ENSI Board, the Swiss Federal Department of the Environment, Transport, Energy and Communications (DETEC), the Swiss Federal Department of Foreign Affairs (FDFA), the Swiss Federal Office of Energy (SFOE), the Swiss Federal Office of Public Health (FOPH), the Swiss Federal Office of Civil Protection (FOCP), the Swiss Nuclear Safety Commission (NSC), the Swiss Accident Insurance Fund (SUVA), the Swiss National Cooperative for the Disposal of Radioactive Waste (NAGRA), representatives from the Leibstadt Nuclear Power Plant and the Gösgen Nuclear Power Plant, as well as members from the NGO "Swiss Energy Foundation" were also organized.

All through the mission the IRRS team received excellent support and open cooperation from ENSI's senior management and staff.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Switzerland's radiation and nuclear safety governmental, legal and regulatory framework and activities within the competence of ENSI against the relevant IAEA safety standards to report on the effectiveness of the regulatory system and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated by ENSI. The mission did not include a comprehensive review of the national regulatory infrastructure for radiation safety of Switzerland, amongst others, medical exposure was not included in the scope. It is expected that this IRRS mission will facilitate improvements in regulatory infrastructure in Switzerland and other Member States, utilising the knowledge gained and experiences shared between ENSI and IRRS reviewers and the evaluation of the Swiss legislative and regulatory framework for nuclear safety, including its good practices.

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

a. providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
b. providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
c. providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
d. promoting the sharing of experience and exchange of lessons learned among senior regulators;
e. providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience in other regulatory practices in the same field;
f. providing the host country with recommendations and suggestions for improvement;
g. providing other Member 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 Member States;
j. promoting the application of IAEA Safety Requirements;
k. providing feedback on the use and application of IAEA Safety Standards;
l. providing feedback on the regulatory implications of pandemic situations.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Switzerland, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 3 to 4 March 2021. The preparatory meeting was carried out by the appointed Team Leader Mr Petteri Tiippana, the Deputy Team Leader Ms Isabel Villanueva, and the IRRS IAEA team representatives, Mr Jean-René Jubin, the IAEA Coordinator, and Ms. Vasiliki Kamenopoulou, the Deputy Coordinator.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of ENSI represented by Mr Marc Kenzelmann, Director General, 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:

- Nuclear power plants;
- Research reactors;
- Waste management facilities;
- Radiation sources application in nuclear facilities;
- Decommissioning;
- Transport of radioactive materials;
- Occupational radiation protection;
- Public and environmental exposure control;
- Waste management;
- Selected policy issues.

As it was agreed, the IRRS mission was also used to exchange between the IRRS team and ENSI experiences on the regulatory implications of the pandemic situations, including in relation to business continuity.

Mr Marc Kenzelmann, Director General of ENSI, presented the national context and legal and regulatory framework in Switzerland, and Ms Annatina Müller-Germanà, Head of ENSI's International Affairs, presented the Self-Assessment Process implemented by ENSI and the main 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 Switzerland from 18 to 29 October 2021.

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

The Swiss Liaison Officer for the IRRS mission was confirmed as Ms Annatina Müller-Germanà.

ENSI provided the IAEA with the Advance Reference Material (ARM) for the review in August 2021. In preparation for the mission, the IAEA team members reviewed the ARM and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on 17 October 2021 at ENSI's Headquarters, conducted 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 18 October 2021, with the participation of the Members of the ENSI Board, and ENSI's senior management and staff. The welcome address was delivered by Marc Kenzelmann, Director General of ENSI, and Mr Andreas Abegg, President of the ENSI Board. Opening remarks were made by Mr Petteri Tiippana. Mr Marc Kenzelmann gave an overview of the Swiss context and an overview of the self-assessment, with cross cutting and main conclusions. Then, the key steps and key aspects of the mission were reviewed by Mr Jean-René Jubin, IAEA Coordinator.

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

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

The IRRS exit meeting was held on Friday 29 October 2021. The opening remarks at the exit meeting were presented by Marc Kenzelmann and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Petteri Tiippana. Closing remarks were made by Ms Anna Hajduk Bradford, IAEA, Director, Division of Nuclear Installation Safety.

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

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Switzerland has a well-defined legislative and regulatory framework for nuclear safety and protection against ionizing radiation. The policy and strategy are codified by different Acts of parliament.

The Federal Constitution of the Swiss Confederation and the federal Acts establish the regulatory framework for the safety of facilities and activities, radiation protection, safe transport of radioactive material, safe management of radioactive waste, decommissioning and emergency planning.

The Nuclear Energy Act (NEA) regulates the peaceful use of nuclear energy and applies to nuclear goods, nuclear facilities and radioactive waste that is generated in Switzerland. It states the basic principles of nuclear safety, defines the licensing procedure, general responsibilities of the licensee, regulations on decommissioning and disposal of radioactive waste and sanctions. In addition, the NEA designates the Swiss Federal Nuclear Safety Inspectorate (ENSI) as the regulatory authority for nuclear safety and security.

The Radiological Protection Act (RPA) applies to all activities, installations, events and situations that may involve an ionizing radiation hazard. It states the fundamental principles of radiation protection, the licensing obligations for the handling of radioactive substances, and the provisions for protecting persons who are occupationally exposed to radiation and for the general population, for permanently monitoring the environment and for protecting the population in the event of increased radioactivity levels.

All significant provisions that establish binding legal rules must be enacted in the form of a federal Act. However, the parliament has, to some extent, the competence to delegate its legislative powers to the executive branches. The government (Federal Council) or ministries (Departments) may issue ordinances containing detailed regulations. Some of the IAEA Safety Fundamentals are considered also by the Nuclear Energy Ordinance (NEO) and the Radiological Protection Ordinance (RPO). Moreover, the NEO also contains provisions on periodic safety review (Art. 34), on demonstrating safety for long-term operations (Art. 34a), on aging management (Art. 35) and on monitoring the state of the art in science and technology and the operating experience (Art. 36) and thus further solidifies the operators' obligation to continuously improve safety during the entire lifetime of a facility and, in particular, an obligation to back-fit nuclear facilities (Art. 22 para. 2 let. g of the NEA).

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

The NEA includes the requirement for the licensee to follow the experience and the state of art in science and technology. NEA and NEO set also various legal provisions relating to the promotion of research and development (especially Art. 86 NEA and Art. 77 NEO), as well as for the education and training of personnel in the areas of safety and security of nuclear facilities. However, these provisions are discretional. The IRRS team found that the long-term building and maintaining of competence in nuclear safety is a concern for Switzerland. Maintenance of competencies of all parties having responsibilities in the area of nuclear safety should be an essential element of the Government's long-term commitment to safety, especially considering the country is phasing out its nuclear power programme and the political environment is not particularly favourable to nuclear technologies (for details, see chapter 1.8).

The responsibility for safety lies with the operator (Art. 22 NEA). Art. 5(1) NEA requires the operator to set up a suitable organisation with qualified personnel and to foster a strong safety awareness. ENSI influences the operators' safety culture through its oversight practice. In this context, in 2016, ENSI prepared a report on oversight practice with the title "Oversight of Safety Culture in Nuclear Installations". The report defines what safety culture is and how it is accessible, and it lays down the characteristics of a good safety culture, the oversight of safety culture and the safety culture of ENSI (more details in chapters 4 and 7).

In Switzerland, the graded approach principle is associated with the principle of "proportionality" that is anchored in the Swiss Federal Constitution. The national policy and strategy for safety as reflected in the laws regulating nuclear energy and radiation protection contain provisions related to a graded approach. The legislation takes account of the risks associated with a facility or activity when defining licensing procedures and specifying the obligations of the licence holder (Art. 12(3), 22(2)(e), 65 NEA, Art. 8 RPO).

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The competence for nuclear safety and radiation protection rests within the Swiss Confederation. This competence encompasses legislation and implementation.

The basic provisions of the legislation governing nuclear safety and radiation protection are set out by the parliament (federal Acts) while regulations are enacted by the Federal Council or Departments (ordinances). In addition, ENSI issues guidelines either in its responsibility as supervisory authority or based on a mandate in an ordinance. Guidelines are support documents and represent the fourth level of Swiss legislative and regulatory framework. They formalise the implementation of legal requirements and facilitate uniformity of implementation practices.

The competent authorities are designated by the federal legislation. Implementing authorities of the NEA are mainly:

- The Federal Council and the Department of the Environment, Transport, Energy and Communications) – DETEC (licencing authority for nuclear facilities),
- The Swiss Federal Office of Energy - SFOE (licencing authority for the handling of nuclear material, licences for the export and mediation of technology including safeguards, also drafting of licences issued by the Federal Council and the DETEC),
- ENSI (regulatory authority for nuclear safety and security).

For nuclear facilities the duties are split between the Federal Council and DETEC on the one hand and ENSI on the other hand; the Federal Council and DETEC formally grant the licences, whereas ENSI provides the technical expertise (by delivering an expert opinion in the form of a safety evaluation report). Once the licence is granted, ENSI supervises the licence holder and issues permits. Permits must always be granted in the frame of an existing licence. Permits enable the regulatory authorities to verify that conditions specified in the licence and relevant legal and regulatory requirements are met during the construction and commissioning process (Art. 75 of the NEO). Permits are also required for modifications of existing facilities when modifications do not deviate significantly from the licence but may have an influence on nuclear safety or security (Art. 65 para. 3 of the NEA). In addition, ENSI is responsible for inspection and enforcement to ensure the facilities' operators fulfil their responsibility to operate their facilities safely. ENSI has also the power to issue orders on necessary and reasonable measures aimed at preserving or improving nuclear safety, radiation protection and security.

If the NEA does not have a specific provision, then the provisions of the Radiological Protection Act generally apply, which regulate radiation protection and apply to all facilities and activities, including those related to the use of nuclear energy.

Implementing authorities of the RPA are:

- the above-mentioned authorities in the field of nuclear energy (licences under the NEA also cover radiation protection, ENSI supervises nuclear facilities with respect to radiation protection and, to a limited extent, also grants licences under the RPA);
- for other situations, activities and facilities that may involve an ionising radiation hazard, the licensing authority is the Swiss Federal Office of Public Health (FOPH). Supervision is conducted by the FOPH for medicine and research applications and by the Swiss National Accident Insurance Fund (SUVA) for industrial applications.

The ENSI Act of 22 June 2007 (ENSIG) establishes ENSI and stipulates organisational principles, tasks and responsibilities of ENSI, the bodies of ENSI, financing and budget, independence of ENSI and accountability of the ENSI Board to the Federal Council.

The safety principles for nuclear safety and radiation protection are embedded both in nuclear safety legislation and regulation (Art. 1, Art. 4(2), Art. 30(3) NEA and Chapter 2 NEO) and in radiation protection legislation and regulation (Art. 1, Art. 9, Art. 10, Art. 17 RPA and Chapter 2 RPO).

NEA (Art. 2 and 3) and RPA (Art. 2) identify facilities and activities that are included within the scope of the framework for safety and the corresponding authorization system. According to the graded approach different authorities grant different licences or permits for nuclear facilities and activities.

Because of the political decision to phase out nuclear power, Art. 12a of the NEA prohibits the granting of a general licence for a new nuclear power plant. The procedure for granting the general licence for nuclear facilities is regulated in Art. 42 ff. of the NEA. The general licence is granted by the Swiss Federal Council and differs from all the other licences because after the experts' evaluation there is a political decision-making process that requires approval of the licence by the Parliament as well as by an optional public vote. The procedure for granting the construction licence for nuclear facilities and licences for geological investigations is regulated in Art. 49 of the NEA. The procedure for granting the operating licence for nuclear facilities, for the decommissioning of nuclear facilities and the closure of deep geological repositories is set in Art. 61 - 63 of the NEA. Involvement of different federal and cantonal authorities and of the public is prescribed for all licences and orders set by NEA.

Following Art. 22(1) of the NEA, the licence holder is responsible for the safety of the installation and its operation. Art. 66 of the NEA regulates the transfer of a licence.

The NEA and the RPA form the legal basis for the regulatory review and assessment. The general requirements for the safety review of nuclear facilities are covered by the NEA, the NEO, the RPA and the RPO. Chapter 4 of the NEA defines the general scope of safety analysis and verifications required to be performed by the licensees over the lifetime of a nuclear facility. These requirements are defined in more detail in Chapter 4 of the NEO.

According to Swiss legal system ENSI cannot issue ordinances as this power is given only to the Federal Council and Departments. However, ENSI as a federal authority has the possibility of creating a legislative initiative if there is a need for adoption or change of law or ordinance. In all cases when a draft law or ordinance affects nuclear safety, ENSI would be formally invited to take part in the legislative procedure (Art. 2 ENSIG).

The NEA and RPO contain provisions on inspection and enforcement and all regulatory decisions can be appealed to the Federal Administrative Court.

The legislation governing nuclear energy, radiation protection and civil protection contains provisions regarding emergency preparedness and response. In addition to nuclear safety, the NEA also governs nuclear security (Art. 5(3) NEA). ENSI coordinates the safety and nuclear security interface internally as the regulatory authority for both (see chapter 11 for details). The NEA as well as the RPA have provisions on offences and corresponding penalties.

The various Swiss authorities with responsibilities for nuclear safety, security, safeguards and radiation protection have well assigned responsibilities by law and coordinate their work regularly (for details on interfaces between DETEC, ENSI and other authorities involved in licensing procedure, see Section 1.8).

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

ENSI is an institution under the public law and is legally, institutionally, politically, and financially independent. ENSI performs its regulatory work autonomously and independently as specified in Article 18 of the ENSIG. This prevents the Federal Council or any other administrative authority from interfering in the regulatory activities of ENSI. Legal disagreements are to be treated only by the Courts.

The ENSIG prescribes organisational principles, tasks and responsibilities of ENSI, ENSI's bodies and their functions and responsibilities, financing and budget, independence of ENSI and its relations to the Federal Council.

In addition, the legislation stipulates the duties and powers of the regulatory authorities (Art. 72 of the Nuclear Energy Act) and ensures that sufficient financial means are available (Art. 83 of the Nuclear Energy Act). This article provides that ENSI is mainly (95%) financed through fees charged to the applicants and licence holders. Further, the Swiss Confederation provides resources for ENSI research activities and compensates ENSI for the services ordered.

ENSI has its own budget which is not subject to the restrictions usually applied to authorities of the federal administration (e.g. it is not bound by the HR plans and requirements of the federal government). ENSI enjoys great flexibility, and it is equipped with the financial means to make available the competences and resources required to fulfil its statutory obligations.

The legal provisions prevent ENSI from being unduly pressured by any political circumstances or economic conditions or by government departments, authorized parties, or other organizations. Regarding nuclear safety and security ENSI is tasked (Art. 73 NEO) with the review of applications for licences and the technical assessment of projects pursuant to Art. 49–63 NEA. The access to the highest levels of government is guaranteed via the ENSI Board that reports directly to the Federal Council. ENSI has not been attributed responsibilities that

might compromise or conflict with the responsibility for regulating the safety and nuclear security of nuclear facilities and activities.

Based on Art. 6 of the ENSI Act the Federal Council approved the Personnel Rules of the Swiss Federal Nuclear Safety Inspectorate (ENSI Personnel Rules). They contain rules on personnel policy and on personnel promotion and development. According to Art. 3 of the ENSI Personnel Rules, ENSI has to take suitable measures to recruit and keep suitable personnel, and to develop and maintain the necessary competence and skills of staff. ENSI is autonomous in implementation of its human resource management.

The IRRS team considers the establishment of ENSI by the law and providing it with the high level of independence and adequate resources to fulfil its statutory obligation without interference from government authorities as a good performance.

The ENSI Code of Conduct prohibits ENSI staff to act or to behave in their professional and private life in a manner that could generate the appearance of a conflict of interest. The staff must obtain permission from ENSI's management prior to taking up a subsidiary activity, regardless of whether the activity is lucrative or not. Further, the IRRS team considers it a good performance that ENSI staff must periodically undergo personal security background tests that could reveal any possible lack of impartiality.

Based on NEA Art. 70 and 71, there are two federal bodies with the primary mission to ensure nuclear safety and to provide safety assessment and expert opinions to licensing authorities, namely ENSI and the Federal Nuclear Safety Commission (NSC). One of the NSC's tasks is to provide a second opinion to the Federal Council and to DETEC on ENSI's safety evaluation report. This could lead to potentially conflicting technical positions of ENSI and NSC in licensing procedures where the Federal Council or DETEC may need to resolve the conflict without the necessary expert knowledge. Moreover, this could create a conflict of interest in safety decisions since DETEC has both regulatory functions as a licensing authority and a general energy supply promotion.

In this regard, the Federal Council and the Swiss parliament reassessed the licensing system of the NEA (Postulate 12.3131 of 12 March 2012). In the final report from 2019, they both concluded that the system of nuclear oversight, enshrined in the NEA, reflects the peculiarities of the Swiss system of government and the concept of plan approval procedures in all infrastructure legislation. The system of checks and balances is embedded in Swiss legal system and the division of roles prevents concentration of power. Existing legislation and case law provide sufficient basis for making correct safety-based decisions in nuclear safety, based on the judgement of the Federal Supreme Court of Switzerland of 28 March 2013, which provided an obligatory legal interpretation of roles of different authorities involved in licensing and regulatory procedures.

According to the judgment of the Federal Supreme Court, the operating licence is the responsibility of the licensing authority (DETEC), but the review of the submitted projects is performed by the regulatory authorities (ENSI). These have the status of a legal body of experts and the decision-making authority, and appeals courts may only deviate from assessments arrived at by ENSI for "good cause". The IRRS team was told that in practice the Federal Supreme Court's judgement makes it virtually impossible for the licensing authorities to disregard ENSI's safety evaluation report for extraneous reasons.

Furthermore, ENSI and NSC are both expert bodies in accordance with the judgement but have established a Memorandum of understanding to define the way NSC's review comments are included in ENSI's decision-making process. According to this protocol, ENSI prepares a draft safety assessment and sends it to NSC for review. The expert discussion between ENSI and NSC would in principle be as long as needed for a consensus to be found. If no consensus is reached, two opinions would be sent to SFOE. According to Art.62.b of the Government and Administration Organisation Act, SFOE would start a formalized settlement of the differences to reach an agreement.

The IRRS team was informed that due to Supreme Court ruling in practice neither SFOE as an authority responsible for drafting the licence nor DETEC as licencing authority will deviate from ENSI's safety assessment or licensing conditions as proposed by ENSI. SFOE, who leads the licensing procedure, may reformulate conditions from the legal point of view but will not interfere with the substance of ENSI´s proposed safety conditions. The IRRS team was informed that for complex procedures, an inter-institutional monitoring group of all relevant federal and cantonal authorities is established (for example, in a case of the Mühleberg NPP decommissioning procedure such a monitoring group was established two years before the formal start of the procedure). The purpose of the monitoring group is to collaborate in order to clarify open questions concerning the procedure and to avoid possible conflict between conditions of different authorities. In the Mühleberg decommissioning procedure SFOE included all conditions proposed by different authorities in the draft order.

The draft order with all conditions is finally reviewed from the General Secretariat of DETEC from the legal point of view before being signed and issued.

The judgement of the Federal Supreme Court also assessed the relationship between licensing and regulatory procedures. In the licensing procedure, the licensing authority (DETEC) assesses (with advice from the competent authorities) whether the prerequisites for a licence are met at the time of licensing. Ongoing supervision must guarantee that safety continues to be guaranteed throughout the entire operating period and that, where appropriate, it is improved by subsequent backfitting measures. The regulatory authority (ENSI) has competence for issuing orders to implement specified backfitting measures and to issue permits to amend the operation licence for activities that may influence safety but do not deviate significantly from the operating licence. If the change deviates substantially from the operating licence, as for example in the case of the renewal of the water concessions of Beznau NPP, an amendment to the licence is required and the same procedure as for granting the licence must be applied. The IRRS team was informed that in practice, operation licence amendments concerning nuclear safety are not common and would be needed mainly for major modifications that would require an environmental impact assessment (for example, a power upgrade of the NPP). The IRRS team was informed that all safety modifications to upgrade NPPs after the Fukushima accidents were backfitting measures and authorized by permits.

As described above, DETEC is the licensing authority in Switzerland in case of construction and operating licences for nuclear facilities. DETEC's roles and responsibilities related to the use of nuclear energy could create undue pressure or constraint on nuclear safety with regards to licensing decisions. However, the judgment of the Federal Supreme Court as well as the concept of transparency and involvement of the public and different stakeholders in the licensing process ensures that decisions concerning nuclear safety in different licensing procedures are based solely on ENSI's safety assessment and therefore practically eliminate the risk of any undue pressure or constraint on nuclear safety. In addition, licensing decisions for new NPPs are not expected under the current legislation implementing the decision to phase out the nuclear power programme.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

Art. 22 of the NEA states that the licence holder is responsible for the safety of the installation and its operation. The responsibility for safety remains with the operator all the time. The operator can delegate tasks, but not the prime responsibility for safety (Art. 30(1)(i) of the NEO).

Art. 11 of the RPA states that anyone who handles or is responsible for a radioactive source must take all measures necessary to ensure compliance with the dose limits.

With regard to radioactive waste, the NEA states that anyone who operates or decommissions a nuclear installation is obliged to safely manage all radioactive waste arising from that installation at their own cost (Art. 31).

Applications for a licence for the transport as well as for the import, export or transit of radioactive waste must be submitted jointly by the consignor, the consignee, the carrier and the transport organiser (Art. 56 NEO). The SFOE is in charge of granting the licence based on the safety and security assessment by ENSI. As license holders the consignor, the consignee, the carrier and the transport organiser are jointly responsible with regard to nuclear safety and security as well as radiological protection (Art. 101 RPO).

Art. 72 of the NEA defines the duties and powers of regulatory authorities. It states that regulatory authorities shall order all necessary and reasonable measures aimed at preserving nuclear safety and security.

In addition, Art. 73 of the NEA states the obligation for the licensees to provide regulatory authorities with any type of information necessary to check the compliance with the regulatory requirements and grant access to the facilities to regulatory authorities.

The NEA states that precautionary measures must be taken that contribute towards an additional reduction of risk insofar as they are appropriate (Art. 4(3)(b)). This principle includes the obligation to continuously improve safety during the entire lifetime of a facility. For instance, the holder of an operating licence shall:

- take measures to ensure that the installation is kept in good condition,
- carry out follow-up inspections and systematic safety and nuclear security evaluations throughout the operating lifetime of the installation,
- in the case of NPPs, carry out a comprehensive periodic safety review,
- periodically report to the regulatory authorities about the condition and operation of the installation,

- backfit the nuclear installation to the necessary extent that it is in keeping with operational experience and the current state of backfitting technology,
- monitor scientific and technological developments and compare operating experience and findings with those of other installations.

The provisions of the NEA on the responsibility of the licence holder for the safety of the installation and its operation implies that having an authorization does not affect the licence holder's prime responsibility for safety as they have the obligation to continuously improve safety during the entire lifetime of a facility.

The IRRS team considers that the Swiss legal system adequately stipulates requirements for the prime responsibility for safety and compliance with regulations.

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

According to Art. 14 to 16 of the Ordinance on the Organisation of the government and the administration (SR 172.010.1), the federal authorities are obliged to collaborate. They have a comprehensive obligation to cooperate with the other federal authorities interested in or concerned by a topic or business, they have to assure the involvement of the interested or concerned authorities in the decision-making process and they also have to include the cantons and other parties (towns, communities) responsible for the execution and implementation of the relevant topics and businesses.

Radiation protection regulation has fixed different general provisions for the coordination of the different regulatory authorities in the radiation protection domain:

- The regulatory authorities shall coordinate enforcement and resolve any uncertainties regarding responsibility with regard to supervision by mutual agreement. They shall meet regularly for this purpose. (Art. 184(5) RPO).
- The regulatory authorities shall make the required documents available to the licensing authorities at any time upon request (Art. 185(2) RPO).
- The regulatory authorities may, by mutual agreement, commission research projects concerning the effects of radiation and radiological protection or participate in such projects.

The IRRS team considers that the various Swiss authorities with responsibilities for nuclear safety, security, safeguards and radiation protection have well assigned responsibilities by law and coordinate their work regularly.

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

For reducing undue radiation risks associated with natural or artificial unregulated sources or with contamination from past activities or events, Switzerland has a system in place to identify such situations and to establish protective actions, including regulatory actions.

The legislation on protection against ionising radiation defines existing exposure situations and the principles to be adopted for establishing protective actions. It sets requirements on existing exposure situations to manage radiological legacies, radon, naturally occurring radioactive material and long-term contamination following an emergency, i.e.:

- Radiological legacies are regulated by Art. 149 to 154 of the RPO;
- Radon is regulated by Art. 155 to 167 of the RPO; a reference and threshold values are set in Art. 155 (public) and 156 (occupational) respectively. The Swiss Federal Council adopted the Radon Action Plan 2021-2030 to support the practical implementation of the provisions of the RPO over the next decade;
- Naturally occurring radioactive material (NORM) is regulated by Art. 168 to 170 of the RPO;
- With regard to long-term contamination following an emergency, the FOPH has to prepare the long-term federal and cantonal measures for the management of effects after the transition from an emergency exposure situation to an existing exposure situation (Art. 171 RPO) in accordance with the decision of the Swiss Federal Council that orders such transition (Art. 141 RPO).

The system of licensing for operation of facilities or for handling of nuclear or radioactive material helps prepare in advance to prevent undue radiation risks associated with unregulated sources (of natural and artificial origin) and contamination from activities or events.

Art. 104 of the RPO defines provisions to detect and regain control of orphan sources. The practical implementation of this article is part of the national Action Plan 2020-2025 to strengthen the radiological security and safety of radioactive material in Switzerland (Radiss). If there is an increased likelihood of orphan radioactive materials being encountered in recyclable materials or wastes, the enterprises concerned are required, when managing or preparing these materials or wastes for export, to inspect them for the presence of orphan radioactive materials using appropriate screening procedures and, if such materials are detected, to secure the recyclable materials or wastes at an appropriate location.

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

The NEA provides comprehensive regulation of all aspects of radioactive waste management. According to Art. 30 of NEA, radioactive waste arising in Switzerland must be managed and disposed of in Switzerland. All the producers of radioactive waste are responsible for its safe management and disposal and have to bear the costs.

The responsibility for conditioning and interim storage of radioactive waste from nuclear facilities remains with the operators. The Swiss Confederation has taken over the responsibility for the collection, conditioning, storage and disposal of radioactive waste generated by the use of radioisotopes in medicine, industry and research. The producers of this kind of radioactive waste are charged a fee for this service.

All radioactive waste is to undergo final disposal in repositories situated in suitable geological formations. The producers of radioactive waste, i.e., the nuclear facilities' operators and the Swiss Confederation (for the waste from medicine, industry and research) have formed the National Cooperative for the Disposal of Radioactive Waste (Nagra), which is responsible for the disposal of all kinds of radioactive waste.

Art. 32 of the NEA sets requirements for the preparation and periodical review of the waste management programme every five years, which must include also a financial plan up to the time at which the nuclear facilities will be taken out of operation.

The latest waste management programme was prepared by Nagra in 2016, a new version will be submitted by the end of 2021.

In order to strengthen the minimization criteria of RW production the Federal Council approved a revision of the RPO and NEO to regulate the decay storage up to 30 years of VLLW.

The NEA and Art. 5 NEO (Sectoral Plan) prescribe a three-step process for the site selection of the disposal of radioactive waste in deep geological formations:

1. Identification of suitable siting regions,
2. Identification of potential repository sites
3. The approval of the selected sites by the Federal Council and Parliament at the end of stage 3.

The process for granting the construction licence is regulated in Art. 15 and in Art. 49 of the NEA and the rules for the granting of the operating licence are set in Arts. 19 and 37 of the same Act.

The site selection process (Sectorial Plan) for a repository for high level waste (HLW) and one for low and intermediate level waste (L-ILW) started in 2008. A repository that combines HLW and L-ILW is also possible. The Sectorial Plan for the national radioactive waste disposal repositories is safety based. Stage 2 was completed in 2018 and the Sectoral Plan is currently in the last of the three stages. The process continues to be open and transparent providing opportunity to all involved stakeholders and to address all possible aspects connected to the siting of disposal facilities.

The IRRS team considers the achieved progress and a wide public participation in the site selection process as a good performance.

The next step in the process will be the announcement of Nagra in 2022 regarding for which site(s) they plan to hand in the general license. The option to use only one site to store all waste is still open. The application of Nagra is envisaged in 2024 while issue of the general licence for the disposal site selection is expected in 2030. The decision to grant a general licence is subject to an optional national referendum.

Operation is foreseen in 2050 for the L-ILW and in 2060 for HLW disposal facility.

During the licensing process for the general licence (2024-2030), an international peer review on the implementation of the National Waste Management Programme could be requested to strengthen the process, to support the regulatory body assessment and to increase the public confidence during the licensing process to grant the general licence.

Concerning the spent fuel management, about 1200 tons of spent fuel have been reprocessed in the UK and in France. All the radioactive waste arising from reprocessing has been returned to Switzerland. Spent fuel and radioactive waste returned from reprocessing is stored in the dry storage building at Beznau NPP (only reprocessing waste) and in the Central Interim Storage Facility of Zwilag. The 2018 Amendment to NEA prohibits further export of the spent fuel for reprocessing. In addition, a spent fuel wet storage facility is operating at Gösgen NPP.

Immediate dismantling is the preferred strategy for decommissioning. However, as indicated in the Guideline ENSI-G17, a deferred dismantling may also be acceptable with sufficient justification.

The Mühleberg NPP is in decommissioning, dismantling phase 1started in September 2020 in accordance with Decommissioning Order granted in 2018 (more details in chapter 5.6).

Furthermore, there are currently four research reactors and one small waste treatment facility in different stages of decommissioning. Four of these five facilities are located at Paul Scherrer Institute (PSI), and the fifth at the University of Basel completed decommissioning and is awaiting formal discharge from the NEA.

According to Chapter 7 of the NEA, funds have been established to ensure the availability of sufficient financial resources for the decommissioning and for the disposal of radioactive waste and spent fuel. The Ordinance on the Decommissioning and Waste Management Funds for Nuclear Facilities defines the allocation of financial resources to cover the costs for the decommissioning and for the final management of radioactive waste and spent fuel. A recalculation of the costs is undertaken every five years, based upon updated technical plans.

1.8. COMPETENCE FOR SAFETY

Currently, Switzerland offers high-quality opportunities for professional scientific and engineering education and training. It also has institutions playing an important role in research. Nevertheless, most of the activities regarding education, training or research are mainly initiated and financed by the nuclear industry. This reflects that the responsibility for this matter is largely delegated to the industry as the provisions related to the promotion of research; education and training (especially Art. 86 of the NEA and Art. 77 of the Nuclear Energy Ordinance) are only discretionary. There is no clearly defined binding obligation of the government to promote research, education and training. Also, due to the pressure to cut public spending the available financial resources are limited.

In addition, the political decision to phase out from nuclear energy will not support further competence development in nuclear safety or in attracting new people into this area. After the decision to phase out, the political awareness for the importance of building and maintaining competence in the nuclear field has diminished, and the issue has become a matter of serious concern.

The IRRS team observed some practical consequences of the reduction of qualified experts in some areas. For example, following the shutdown of the German nuclear fleet, NPP operators in Switzerland noted a reduction in the number of trained and qualified Radiation Protection (RP) technicians available in Switzerland. The IRRS team was informed that many foreign experts, especially from Germany, are contracted by Swiss stakeholders in many areas of nuclear and radiation safety. As a result of the lack of RP technicians, Swiss NPP operators turned to outside contract companies to hire and train RP technicians and thus created two separate groups of RP technicians receiving different pay rates while performing essentially the same job functions. ENSI expressed concern to the IRRS team that the pay inequity had a negative impact on safety culture.

There is no general obligation for the parties with responsibilities for nuclear and radiation safety to take measures for building and maintaining competences. However, the parties involved in ensuring safety make efforts for building and maintaining competences on a voluntary basis.

In recent years (2017 to 2020) ENSI allocated on average approximately 5.4 million Swiss Francs per year for regulatory safety research. The Energy Research Masterplan of the Federal Government 2021-2024 developed by the Federal Energy Research Commission (CORE) and approved by the Government sets the importance of maintaining know-how in the nuclear energy field, both for the safety of the operating NPPs and for

decommissioning, dismantling and long-term radioactive waste management. Some progress has been achieved in the area of education by retaining the nuclear engineering master's studies in the two universities ETH Zurich and EPF Lausanne (joint programme, in association with the Paul Scherrer Institute).

Although there are some measures taken in Switzerland in the area of nuclear energy research, the government has not holistically evaluated the needs for building and maintaining the competence on nuclear safety of all different parties having responsibilities for nuclear and radiation safety, and particularly in the context of the long-term operation perspective. An overarching strategy should be developed by the government for implementing a national policy including inputs from all relevant stakeholders such as the Government, Cantons, ENSI, Research Institutes and Universities, and the representatives from the nuclear industry.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *As of today, Switzerland has not systematically evaluated the needs for building and maintaining competence in the nuclear field and, as a result, there is no overarching strategy to fulfil those needs. It remains a major challenge to ensure that sufficient means are provided for building and maintaining the necessary competences, due to a political environment not particularly favourable to nuclear issues and in light of the pressure from cuts in public spending.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 2.3. states that** *"National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following: (…)* *(d) The need and provision for human and financial resources;"*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 11 states that** *"The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities."*
(3)	**BASIS: GSR Part 1 (Rev. 1) para 2.34. states that** *"As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available."*
R1	**Recommendation: The Government should evaluate the needs for building and maintaining competence of the parties that have responsibilities in relation to safety of facilities and activities in the near, mid-term and long-term future. It should then establish the appropriate strategy to fulfil those needs.**

1.9. PROVISION OF TECHNICAL SERVICES

According to the provisions of the Radiation Protection Act, Swiss federal offices are mainly in charge of providing technical services relating to safety such as environmental monitoring, and equipment calibration.

Further, anyone wishing to operate a personal dosimetry laboratory must obtain official approval. The personal dosimetry laboratory may be run by the operator of a nuclear facility or an external contractor. Art. 66-71 RPO regulate the requirements, the approval procedure, duties and obligations of personal dosimetry services. A Central Dose Registry is maintained by the FOPH.

Based on Art. 17 of the Radiation Protection Act, environmental monitoring of radioactivity is mainly performed by the FOPH, while ENSI monitors ionizing radiation and radioactivity in the vicinity of nuclear facilities. Cantons monitor radioactivity in foodstuffs and in consumer products of daily use (Art. 191(4) of RPO).

Calibration of equipment is performed by the Swiss Federal Office of Metrology or by a body recognised by this authority. The Ordinance on Measuring Instruments for Ionising Radiation states requirements regarding calibration and verification of equipment used in the field of ionising radiation.

1.10. SUMMARY

Switzerland has a well-defined legislative and regulatory framework for nuclear and radiation safety.

Maintenance of competence in nuclear safety for all parties having responsibilities on this matter should be essential element of the Government to express long-term commitment to safety. After evaluating the needs for building and maintaining competence of all involved stakeholders in the nuclear field the, Government should establish the appropriate national strategy to fulfil those needs.

ENSI is established by the ENSI Act as an independent regulatory authority for nuclear safety and security and is provided with adequate resources to fulfil its statutory obligation without interference from government authorities, which is considered by the IRRS team as a good performance.

The ENSI Code of Conduct prevents conflict of interest for ENSI staff, and ENSI staff must periodically undergo personal security background tests, that could indicate a possible lack of impartiality, which is considered by the IRRS team as a good performance.

The Swiss legal system ensures that decisions in licensing procedures are based solely on ENSI's safety assessment and therefore practically eliminate the risk on any undue pressure or constraint on nuclear safety.

The IRRS team considers the achieved progress and a wide public participation in the site selection process for the disposal of radioactive waste in deep geological formations as a good performance. Switzerland is encouraged to invite an international peer review on the implementation of the National Waste Management Programme to further strengthen the process.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Switzerland is signatory of various international conventions, treaties and agreements in the field of safety and nuclear security. In the area of multilateral cooperation, Switzerland is a contracting party of quite a number of conventions, including the Convention on Nuclear Safety (CNS), the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention), the Convention on Early Notification of a Nuclear Accident, the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, the Convention on the Physical Protection of Nuclear Materials (CPPNM) and its Amendment (CPPNM/A). Among these conventions, ENSI leads the Swiss delegations in the CNS, and the Joint Convention. In the field of CNPPNM/A, FDFA, SFOE and ENSI, have shared responsibilities and contributions. SFOE is in the leading role for nuclear policies of Switzerland and those are being implemented through the main organisations, e.g. IAEA and Nuclear Energy Agency NEA. In the area of bilateral cooperation, Switzerland has developed and maintains numerous relationships with other countries, including e.g. bilateral commissions with Germany, Italy, France and Austria on nuclear safety matters and emergency preparedness, or a bilateral agreement with the USA on the exchange of information in nuclear safety research.

The Code of Conduct on the Safety and Security of Radioactive Sources is implemented in Switzerland primarily through the provisions in the Radiation Protection Act (RPA), the Radiation Protection Ordinance (RPO) and related ordinances. The Code of Conduct on the Safety of Research Reactors is also implemented primarily in the Nuclear Energy Act (NEA) and the Nuclear Energy Ordinance (NEO).

Switzerland participates in more than 70 international commissions and working groups of the OECD/NEA, IAEA, WENRA and other institutions and ENSI represents Switzerland in all relevant commissions related to international nuclear safety and security. In addition, ENSI participates in all IAEA nuclear safety and security standards committees. The IAEA Safety Standards as well as the WENRA Safety Reference Levels (SRLs) are reflected in the Swiss nuclear safety legislation and in ENSI's regulatory guidelines.

Regarding international peer review activities, ENSI regularly provides experts to serve in various international peer reviews such as IRRS, ARTEMIS and IPPAS. Furthermore, ENSI is legally required to host international review missions periodically. ENSI also participated voluntarily in the EU stress tests and the EU topical peer reviews.

ENSI dispatched a permanent member of its staff to the Swiss Mission for the International Organisations in Vienna and sends employees to regulatory bodies of other countries for learning purposes in accordance with its personnel exchange policy. ENSI inspectors regularly participate in so called "cross-inspections" as observers, which are conducted in other countries. Similarly, ENSI organizes cross-inspections in Switzerland with the participation of foreign inspectors as observers.

After the Fukushima-Daiichi accident, ENSI created the section for international affairs. Based on a senior management policy decision, ENSI became very active in cooperating with the European and the international community. ENSI devotes a lot of effort to international cooperation because it is beneficial for enhancing nuclear safety, radiation protection and nuclear security in Switzerland. This active participation in and contribution to international cooperation is continuing, and ENSI's efforts to realize and keep this state of affairs are considered to be a commendable good performance.

ENSI has a "Strategy for International Cooperation" which was drafted in 2014 and is intended to be updated soon. It lays down the aims, means, roles and responsibilities within ENSI for international cooperation in nuclear safety and security. This strategy contributes to ENSI's active participation in international cooperation. However, there is a concern that the political decision to phase out Swiss nuclear power may have a negative effect on ENSI's current positive attitude to international cooperation. For instance, new technologies in the area of nuclear power generation which would contribute to maintain motivation and competence of ENSI's technical staff necessary for the safety and nuclear security of existing nuclear power reactors, could be an area of such concern. In this context, the policy of ENSI's senior management for international cooperation is important and efforts for coordination by the section for international affairs and contributions by technical staff are expected to maintain this good performance in the area of international cooperation.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

ENSI is collecting operational and regulatory experience (OEF) through various international frameworks and disseminates its own OEF to other countries internationally. Thus, ENSI participates in the Incident Reporting System for Nuclear facilities of the IAEA, the European Clearinghouse, the KWU Regulators Group, working groups of the OECD NEA/CNRA and has bilateral contacts with other regulatory bodies, especially with the neighbouring countries.

The NEA, NEO and ENSI's regulatory guidelines include requirements for event notifications. NEA and NEO also require various obligations of the license holders, such as establishing an interdisciplinary group that investigates events, defines corrective actions and follows their implementation, reviewing event information available through different channels, keeping track of advances in science and technology, reporting insights gained from the reviews to ENSI in certain intervals and so on.

As part of its management system, ENSI established a process of event investigation that includes the independent assessment and classification of all reported national events by an ENSI team of experts from different fields. Furthermore, ENSI reviews information on international events as well as insights from safety research. In some cases, ENSI prepares reports on its examination and response actions. However, the IRRS team identified that ENSI's management system guidance on updating ENSI's regulatory guidance document does not include the consideration of relevant international experience as a criterion for revising the guidelines (see chapter 6 for details).

ENSI periodically conducts meetings with license holders to discuss the events that occurred at their facilities and present ENSI's assessments of the events. Using the opportunity of those meetings, ENSI shares the results of its review and analyses on the international OEF as well as insight from safety research and development.

2.3. SUMMARY

Switzerland is very active in cooperation at the international level, both bilaterally and multilaterally. Thus, Switzerland is a signatory of nuclear related conventions, and it actively participates in various bilateral and multilateral international cooperation initiatives. ENSI represents Switzerland in nuclear safety and security related activities and through those activities, collects and shares relevant OEF.

ENSI has a process in its management system to collect and review domestic and international OEF and reflects the outcomes from the review in its regulatory actions and, as appropriate, in requirements to the licensees. However, the IRRS team identified an area for improvement related to the use of international operating experience triggering revision of the ENSI guidelines.

ENSI participates actively in international cooperation, and contributes to various international agreements. The IRRS team considers this as a good performance.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

ENSI is an independent authority constituted under ENSI Act. It is subordinate to the Federal Council and is supervised by the ENSI Board. The election, composition, independence and duties of the ENSI Board are governed by the ENSI Ordinance. The ENSI Board consists of up to 7 members elected by the Federal Council. The ENSI Board focuses on strategic objectives, adopts strategies and supervises ENSI's work. It neither makes regulatory decisions nor has the legal authority to overturn regulatory decisions taken by the ENSI's executive management.

ENSI itself is managed by ENSI's Executive Board. Currently there are 5 members in ENSI's Executive Board. The members are elected by the ENSI Board. The tasks of the Executive Board are fixed in ENSI's rule of organisation. ENSI is structured into six different divisions with clearly assigned tasks and duties.

Within the federal administration ENSI is linked to the Federal Department of the Environment, Transport, Energy and Communications (DETEC). This link is relevant to locate ENSI within the administrative structure. With regard to ENSI's regulatory duties and responsibilities particularly on ENSI's decisions concerning safety, DETEC does not have the authority or the possibility to overturn these decisions or the authority to instruct ENSI. Due to this provision, there is no conflict of interest observable (roles and responsibilities between ENSI and DETEC are further discussed in Chapter 1.3 in this report).

ENSI is funded mostly by fees paid by the license holders. Based on the ENSI Act, ENSI can charge all necessary fees to applicants and licensees. The rest of ENSI's budget is provided to ENSI by the Swiss Federation as compensation for the services ordered, e.g. from answering questions from the public, parliamentary inquiries and to fund regulatory research activities.

In 2016 ENSI did a comprehensive systematic analysis of the manpower requirements planning and the allocation of resources. To evaluate the essential skills properly ENSI took into account the number of activities and facilities, the tasks and duties of ENSI and other aspects, e.g. the resources needed for ENSI's integrated safety assessment procedure. The allocation of resources and the underlying strategy was re-evaluated in 2019.

ENSI uses a set of performance indicators to measure the effective fulfilment of its statutory obligations. These indicators cover four fields of activity: management, assessment of facilities, surveillance of operations and support. The indicators were evaluated by the executive board, the results were presented to the staff and the ENSI Board. According to the results the allocation of staff and finances can be reassessed and as needed revised.

The IRRS team was informed that ENSI has considered a graded approach in the process of allocating resources. The use of a graded approach is described generally in ENSI's strategy document related to the integrated Safety Assessment. In practise the graded approach is reflected in the organisational structure (separate division with a large amount of resources for NPPs), in the requirements in the regulations and guides (Guideline ENSI-G02 for NPP versus Guideline ENSI-G23 for other facilities) and in ENSI's planning and performance of inspections (dependent on the risk of the facility).

The IRRS team concludes that due to its position within the federal administration and the legal framework as it is stated in the ENSI Act and ENSI Ordinance, ENSI is institutionally, financially and politically independent. Within ENSI's procedure according to the allocation of resources a graded approach was considered in a traceable way.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

Due to its position within the administration and the legal framework stated in the ENSI Act and the ENSI ordinance, ENSI is independent in its decision making. ENSI is functionally separated from entities having responsibilities or interests that could unduly influence its decision making. Although ENSI is administratively under DETEC, the IRRS team concluded that this administrative link does not compromise ENSI's independence and is therefore adequately separated from authorities that are responsible for the energy policy (DETEC) and from federal licensees (PSI, EPFL).

The conditions for interactions with authorized parties, for example during the assessment, are specified in ENSI's management system. Necessary technical discussions are allowed but have to be formally documented.

ENSI has the authority to intervene according to the NEA. ENSI can order all necessary and reasonable measures aimed at preserving nuclear safety and security. In the case of immediate safety or radiological threat ENSI may mandate all necessary measures even if they deviate from the issued license or order.

ENSI has the discretion to manage its overall budget and to allocate its financial resources to its various regulatory activities according to its need. ENSI is managed according to business management principles; it is only obliged to respect basic administrative requirements.

There are several procedures in place to preserve the integrity of the staff within ENSI. It is the responsibility of ENSI's section heads to make their staff aware of issues of independence. The issue is also a topic addressed during training activities of ENSI's inspectors. ENSI has established a code of conduct with principles and instructions associated with conflicts of interest that may arise in connection with ENSI activities. The code of conduct is an annex to all employment contracts for ENSI staff and therefore mandatory for the staff. In addition, there is the oversight of ENSI's activities by the ENSI Board and periodic internal and external audits of ENSI's core processes.

The IRRS team concludes that ENSI is effectively independent in performing its regulatory functions.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

There have not been any significant changes in ENSI's organisational structure during the recent years. The total number of employees is nearly unchanged. The allocation of employees in the 6 divisions has not been substantially changed.

The ENSI Executive Board evaluates the ENSI staffing situation continuously within their periodic meetings. The staffing situation is an agenda item for each meeting of the executive board. Twice per year there is a detailed evaluation of the staffing situation during the conferences of the executive board.

The current staffing levels and competencies are mainly based on a detailed evaluation carried out in 2016 and re-evaluated in 2019. For these evaluations all divisions assessed their staffing situation in detail based on actual situations and tasks and duties at the time. They also considered predictable future developments and challenges. Based on the preparatory work of the divisions the executive board took a final decision.

In the field of staffing and maintaining competence ENSI is facing several challenges mainly due to the political discussions to phase out the nuclear power programme in Switzerland. In order to achieve its goals ENSI has clearly recognized that it relies on the knowledge, competence and commitment of its employees. ENSI therefore developed in 2019 a comprehensive Human Resources (HR) Strategy to face the related challenges. This strategy was discussed with the ENSI Board and implemented accordingly. The HR Strategy contains ENSI's policy and strategy and related sub processes for recruitment, new employee introduction, employee qualification, staff development, regulations for leaving the company and the annual planning and year end procedures.

To underline this strategy with more concrete activities, ENSI developed the Personnel Development Concept. This concept was discussed with the ENSI Board and has been implemented. Within this concept the tasks and responsibilities for employees, managers and the executive board are clearly addressed and described. According to the concept the Executive Board determines strategically the relevant competence requirement for the performance mandate and the overarching goals for the following year's planning, reviews the focal points to be promoted, adjusts them if necessary and breaks them down to the relevant staff groups. In addition to this strategic process, the basis for determining the individual training and development needs is provided by the target agreement, performance appraisal and promotion discussions between line managers and employees.

There are several parts of the Personnel Development Concept to be highlighted:

- Development Centres: programme available for employees with potential for the next target positions;
- Parallel positions: ensuring the transfer of expertise;
- Leadership training: Leadership courses and leadership circles;
- Transfer of practical experience: specials trainings.

ENSI has a detailed catalogue of competencies required for different expert positions. The evaluation of further education of staff members is based on this catalogue and the individual needs of staff members. The education programme for individual staff members is a mandatory part of the annual target agreement discussions. The education programme is agreed by the supervisor and staff member.

In 2020 an internal group "Training Concept on nuclear technology issues and regulatory law" was launched. The aim of the training concept is to ensure a uniform level of knowledge for the supervision of nuclear safety of Swiss nuclear facilities. The training shall be conducted mostly by ENSI staff. External training may be included if available and better suited than achievable by ENSI staff. The concept shall specify the topics of necessary training units, training goals, time budget, periodicity of repetition, target audience, and the ENSI section responsible for training of the specified topics.

A main training concept outlining the general framework as well as specific topics and more detailed concepts are currently drafted.

The training concept is a first step towards a comprehensive knowledge transfer and management programme in nuclear technology issues and regulatory law. Therefore, ENSI management decided that a broad knowledge management project shall be launched. It shall include:

- development of the aforementioned training concept on nuclear issues and regulatory law and of corresponding training material;
- development of a section dedicated to specific training concepts and training material;
- development of a training concept for general competences such as leadership and, project management;
- systemization of exchange of experiences from different sources (e.g. projects and international exchanges) and distribution of corresponding insights;
- establishment of informal channels of knowledge transfer for implicit knowledge (knowledge not easily documented in written / sketched form);
- compilation of explicit knowledge (documented knowledge) including efficient query possibilities, data security and correctness, responsibilities for data correctness.

The corresponding knowledge management project plan is scheduled to be submitted to ENSI management for approval before end of 2021.

The IRRS team interviewed the chairperson of ENSI's staff committee. The staff committee is elected by the employees of ENSI and consists of six members, with all ENSI-divisions represented. The staff committee has periodic meetings with the Director General of ENSI. The chairperson stated that there is a frank, open and trustful relationship between the staff committee, the Human Resources Department and the Director General of ENSI. Furthermore, it was stated that the staff committee was involved in the process of developing the Personnel Development Concept and before implementation the staff committee gave a written statement to the Executive Board of ENSI. Within this statement the staff committee gave a favourable opinion for the personnel development concept.

The IRRS team concludes that ENSI has identified in a traceable way the required number of personnel and competencies to fulfil their regulatory functions. Currently ENSI has an adequate number of personnel and the competencies needed. The IRRS team considers that the Personnel Development Concept as prepared and implemented is a good performance. The Personnel Development Concept seems both comprehensive and the contents of the concept reasonable to the IRRS team.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

According to NEA, ENSI can sign contracts with external experts for support in relation to its oversight activities. ENSI can use external experts if there is not enough in house knowledge or internal resources to deal with a topic. There is a related procedure in the Management system to be followed by contracting experts. Within this procedure there are two main criteria listed to ensure that ENSI concludes only contracts with independent experts devoid of conflict of interests:

- Experts must not work in a segment of an organisation which is overseen by ENSI;
- Experts must not assess parts or systems of a nuclear installation, which is designed, built or assessed by themselves on behalf of supervised entities.

However, these criteria do not rule out in all cases any other business relations between ENSI's experts and the authorized parties, e.g. research contracts or consulting. The IRRS team therefore suggests to revise the set of criteria to ensure that only independent experts devoid of conflicts on interests are contracted.

The most relevant expert organizations contracted by ENSI were the Paul Scherrer Institute (PSI), the Swiss Association for Technical Inspections and Engineering companies. Other contracts have been established with engineering, research and academic institutions as well as with competent individuals. Mainly the fields civil engineering, seismic hazard assessment, deterministic safety analysis, probabilistic safety analysis and accident management are covered. The total amount of contracted experts in the last three years was about 60 person years annually. In relation to the amount of ENSI staff (about 150 employees) and ENSI's internal competences ENSI can take the position as an intelligent customer.

With respect to the relationship between ENSI and the PSI, the IRRS team identified two possible conflicts of interest. The first one lies with the fact that PSI provides also NPPs operators with technical support. This could lead to a situation where ENSI would ask PSI's opinion on a technical subject for which PSI would have already advised the operator and so the analysis would not be independent. Because of the multiple-year contract between ENSI and PSI, PSI is obliged to ask permission from ENSI before contracting with NPP operators. The second potential conflict lies in the nature of the relationship between ENSI and PSI: regulatory body-authorized party and client supplier. Considering the size of the country, this issue seems difficult to fully avoid. Nevertheless, ENSI should remain vigilant on this issue.

The IRRS team concludes that ENSI has the ability to contract external support organizations as needed. ENSI has the internal competence needed to act as an intelligent customer. The relationship of ENSI towards the installed advisory bodies is described clearly and does not compromise ENSI's ability to evaluate safety relevant topics independently.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The criteria used in ENSI's procedure for contracting experts do not rule out in all cases any other business relations between the contracted experts and the supervised entities, e.g. research contracts or consulting.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.20. states that** *"Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services. If this is not possible domestically, then the necessary advice or assistance shall be sought from organizations in other States or, as and where appropriate, from international organizations which have no such conflicts of interest."*
S1	**Suggestion: ENSI should consider revising the set of criteria used in the contracting procedure to ensure that only independent experts devoid of conflicts of interests are contracted.**

The federal government has installed two commissions to provide a second opinion for nuclear safety matters:

- Nuclear Safety Commission (NSC);
- Expert Group on Radioactive Waste Disposal (EGT).

Further the Commission for Radiological Protection and Monitoring of Radioactivity (CRP) provides advice on topics related to radiation protection.

The NSC advises the Swiss Federal Council and DETEC. The NSC can also comment on ENSI's safety evaluation report and on a voluntary basis on ENSI Guidelines. ENSI can ask for a NSC position on specific topics. The relationship between ENSI and the NSC related to safety evaluations is described in a memorandum of understanding to define the manner in which NSCs reports are included in ENSI's process of decision making. In the case that there are different positions from ENSI and NSC, it was stated to the IRRS team from ENSI, DETEC, SFOE and NSC that DETEC/ SFOE will first ask for additional consultations between ENSI and NSC. It was demonstrated to the IRRS team for a single case that this procedure was applied. In case consultations would still end up in different positions, DETEC would need to respect ENSI's position as per Supreme Court ruling (see chapter 1.3).

The relationship between ENSI and the EGT is regulated in the sectoral plan procedure for deep geological waste repositories. EGT supports ENSI and provides comments on geological and constructional issues.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

One main basis for the relationship between the regulatory body and the authorized parties is described in the ENSI process Inspection/Operation surveillance. According to this process, ENSI holds regular meetings on different levels with the authorized parties. During these meetings, current nuclear safety issues, possible

problems in the relationship between ENSI and the authorized party can be addressed at an early stage, discussed and solved, as applicable. The preparation and documentation of these meetings follow a given structure. In addition, expert discussions with the licensees on specific topics are organized regularly by ENSI. ENSI's policy is to discuss and solve issues when possible at working level. Otherwise, the issue goes up to a higher level.

ENSI has designated non-resident site inspectors or coordinators for each nuclear facility. These inspectors and coordinators play an important role as a key contact in the formal but also informal communication with the authorized party.

There are also more formal interactions between ENSI and the authorized parties, such as:

- the notification of decisions from ENSI;
- consultation process preparing decisions and guidelines;
- verification and assessment of the authorized parties' compliance with the legal and regulatory requirements.

For all of these formal interactions there are detailed procedures within ENSI's management system. All regulatory decisions are documented in formal letters and reports. For each decision the regulatory basis is stated in the letter or report. Because of the detailed discussions before issuing the letter there is generally no explanation necessary. If there is exceptionally a need for such an explanation ENSI organizes a meeting.

The IRRS team met representatives from authorized parties (NPP). This meeting provided an opportunity to the IRRS review team to discuss the interactions of authorized parties with ENSI, including their comments on ENSI's activities and decisions.

The IRRS team concludes that the relationship between ENSI and the authorized parties seems to be Frank, open and transparent. The policy of ENSI to discuss safety relevant issues in detail in an open constructive atmosphere with the authorized parties improves the effectiveness of ENSI's oversight.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The ENSI regulatory process is a formal process with several different instruments that are used to ensure that the process is implemented consistently and with management control.

ENSI's decision making process is well defined and relies substantially on the applicable regulatory basis which consists of acts, ordinances, guidelines and technical standards such as norms. This basis is public unless its content is confidential for security reasons.

For all of ENSI's decisions, the basis for this decision has to be set up clearly. ENSI has installed a system of dual control for documents issued to the authorized party. Every letter with regulatory decisions has to be signed by the person who is responsible for the correctness of the content and a person responsible for the consequences of the document. In many cases, one of the signatories must be a division head or the Director General of ENSI. The dual control of documents improves quality and correctness and prevents subjectivity.

To ensure that the regulatory control is stable and consistent ENSI uses the procedures and processes of its management systems and management reviews. ENSI's executive management board conducts twice yearly reviews of the staff performance. In addition, ENSI is supervised by the ENSI Board.

The IRRS team concludes that the concurrence of these processes provides a high level of consistency in the decision making and ensure the stability and consistency of ENSI's regulatory control.

3.7. SAFETY RELATED RECORDS

Swiss legal provisions and ENSI guidelines specify the requirements for recording and archiving documentation regarding construction and operation of nuclear facilities, regulatory activities, occupational doses and inventories of radioactive sources, waste and spent fuel.

The provisions define in detail which data have to be recorded by which organisation (ENSI, FOPH, SFOE and operators) and for how long the records have to be archived.

Related to the safety of facilities and activities the NEO obliges the licensee to document the operation of the installation on the basis of records fixed in Annex 3 of the NEO. Guideline ENSI-G09 contains detailed requirements related to Annex 3. The licensee is obliged to archive the documentation until completion of the

decommissioning or until closure of the installation. All documentation must be handed over to ENSI or DETEC after the decommissioning or after closure of the installation.

ENSI has installed a clear procedure for the reporting of events. Based on the requirements within NEA and NEO, the Guideline ENSI-B03 specifies the details of the reporting procedure including the notification of events and findings, the classification and the timing for the reporting, Loss of sources and release of radioactivity are also addressed in this guideline. ENSI validates the notification and will forward it as specified in ENSI's management system. If the incident classification is INES>2 the notification will be forwarded to IAEA as required in the RPO.

There is a general obligation in the NEA requiring owners of nuclear material to monitor their inventories of nuclear materials, maintain records and report to the relevant regulatory authorities on a periodic basis. This obligation is also valid for the licensee of a deep geological waste repository. In addition, the NEA keeps records of nuclear materials and radioactive wastes in Swiss nuclear facilities.

Several articles of the NEO define additional reporting obligations of the licensee. Guidelines ENSI-B02 and ENSI-B03 provide detailed guidance on these obligations.

The RPO requires the licensing authority to maintain a Central Dose Registry and an inventory of license holders and of the high-activity sealed sources in their possession.

The IRRS team concludes that in principle there are sufficient provisions in the Swiss regulatory framework in place to ensure that adequate records and inventories related to the safety of facilities and activities are established and maintained. Nevertheless, the IRRS team identified one area for improvement in the area of decommissioning (Section 9.6 of the report).

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

According to the NEA and the NEO, ENSI must regularly inform the public about the conditions of the nuclear facilities and about matters related to nuclear goods and radioactive waste, as well as about special events. Furthermore, ENSI informs the public in the case of special events and findings that do not fall under these conditions.

To fulfil these legal obligations ENSI has implemented a communication strategy defining main objectives and main communication activities. Within the strategy ENSI has considered a broad variety of external stakeholders.

ENSI's main communication tools are:

- ENSI's website as leading tool;
- Annual reports (Regulatory Oversight Report, Radiation Protection Report, Research and Operational Experience Report);
- Additional reports (current topics or decisions on nuclear safety);
- Events and meetings with representatives of municipalities, cantons, NGO, NPP operators and authorities (Technical Forum on Nuclear Power Plants, Technical Safety Forum).

Furthermore, the ENSI Board addresses a yearly Business Report to the Federal Government to discharge its duties. The report is then published.

In addition, ENSI uses "flanking communication tools" such as social media (LinkedIn, Twitter). ENSI is announcing new website contributions and providing information on events and on ENSI's attendance in events. Also, ENSI publishes a new series "Number of the week" to expand presence and provide insights into ENSI's tasks.

ENSI has a crisis communication concept, prepared working instructions, checklists for various types of crises, telephone lists and practised procedures. An emergency exercise is held annually at all nuclear facilities. The Communication Section of ENSI takes part in these exercises and evaluates the corresponding communications work of the nuclear power plants.

The ENSI Board has commissioned ENSI to review and adapt the current communication strategy. The first step of this review was interviews with representatives of the various stakeholder groups and spontaneous street interviews. This work was done in cooperation with a market research institute. The most important indications from this survey were:

- Low level of awareness of ENSI as an organization;
- Intact trust in Swiss authorities;
- Potential for cross media use of information and communication channels; and
- The fact that the more someone knows about ENSI, the greater their interest in ENSI becomes.

ENSI is currently evaluating the results in detail and preparing a new communications strategy.

The IRRS team concludes that ENSI has a comprehensive communication strategy. ENSI's information services go beyond the legal requirements and are proactive. ENSI's activities in the revised strategy will be even more customer oriented and include detailed dialogue group oriented goals, messages and activities for the different stakeholder groups. Implementing this strategy will further improve its effectiveness as a regulatory body. The IRRS team considers ENSI's activities as a good performance and encourages ENSI to continue along this path.

The IRRS team had a meeting with representatives from a local Non-Governmental Organization (NGO). This meeting provided an opportunity to the IRRS team to discuss the interactions of ENSI with an interested party, including in relation to the information provided by ENSI and meetings held in order for the NGO to express its concerns and discuss its opinions.

In case there are special occurrences at the nuclear facilities, the Swiss regulatory framework sets obligations to inform the public only to ENSI, but there is no obligation for the authorized parties to inform the public in such cases. ENSI has identified this point in their self-assessment as an area for improvement.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Swiss regulatory framework sets obligations to inform the public only to ENSI, but there is no obligation for the authorized parties to inform the public about safety relevant occurrences.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.68. states that** *"The authorized party shall inform the public about the possible radiation risks (arising from operational states and accidents, including events with a very low probability of occurrence) associated with the operation of a facility or the conduct of an activity. This obligation shall be specified in the regulations promulgated by the regulatory body, in the authorization or by other legal means."*
R2	**Recommendation: The Government should include an obligation in the regulatory framework for the authorized party to inform the public about safety relevant occurrences in their facilities.**

3.9. SUMMARY

The IRRS team concludes that due to the regulations in the ENSI Act and ENSI Ordinance, ENSI is institutionally, financially and politically independent.

Currently ENSI has an adequate number of personnel and the competencies needed. The process for how the Personnel Development Concept was prepared and implemented is considered as a good performance by the IRRS team. The Personnel Development Concept is comprehensive and effective for managing the human resources and competences of ENSI.

ENSI has the ability to mandate external support organizations as needed, and, based on its internal competence, can act as an intelligent customer. The relationship of ENSI towards the established advisory bodies is described clearly and does not compromise ENSI's ability to evaluate and decide on safety relevant topics independently.

The relationship between ENSI and the authorized parties is frank, open and transparent. The policy of ENSI to discuss safety relevant issues in detail in an open and constructive atmosphere with the authorized parties improves the effectiveness of ENSI's oversight.

The ENSI regulatory process is a formal process with several different instruments that are used to ensure that the process is implemented consistently and with management control. The IRRS team concludes that the concurrence of these processes provides a high level of consistency in the decision making and ensure the stability and consistency of ENSI's regulatory control.

In principle there are sufficient provisions in the Swiss regulatory framework in place to ensure that adequate records and inventories related to the safety of facilities and activities are established and maintained (see suggestion related to decommissioning in chapter 9).

ENSI has developed and implements a comprehensive communication strategy. ENSI's communication activities go beyond the legal requirements and are proactive. Implementing ENSI's new communication strategy will further improve its effectiveness as a regulatory body. The IRRS team considers ENSI's activities as a good performance and encourages ENSI to continue along this path.

The IRRS team identified two areas for improvement related to ENSI's liaison with support organizations and one more principal topic related to the missing legal requirement for authorized parties to communicate directly to the public about safety related events in their facilities.

4. MANAGEMENT OF THE REGULATORY BODY

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The leadership and managerial commitment to safety has been well demonstrated by ENSI. The key document for the management system is the yearly performance agreement between the ENSI Board and ENSI's Executive Board. This agreement includes strategic goals based on the concept of fundamentals of the "Integrated Oversight" and the ENSI's Mission Statement declaring safety as the top priority. Safety aspects are discussed by the line managers on a regular basis in the frame of divisional and executive meetings.

The management system assigns responsibilities for the different tasks and provides guidance on good attitudes and behaviour. The overall responsibility for implementation and monitoring of the effectiveness of management system is assigned to the Chief Quality Officer of ENSI and the responsibility for the development and improvement of the main processes are assigned to the process owners through their Job Descriptions (JD's). The responsibility and commitment of managers at all levels with regards to the implementation of management system was evident from the well-defined and documented strategies, goals, plans and policies of ENSI.

Various policy documents and projects were established by ENSI which clearly demonstrate its leadership for and commitment to safety by its senior management, including setting goals, defining individual and institutional expectations and encouraging a questioning and learning attitude.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The Organizational structure of ENSI and their core, support and management processes and responsibilities of the individuals are well defined in the management system and are in line with the organizational goals and objectives.

The Management System includes all kinds of activities including cultural aspects, safety, health and environment as well as legal requirements, in an integrated manner. As a general rule, every decision is reviewed by either the line manager or an expert. In some fields there are specific subprocesses, e.g., decision making or conducting organizational changes. They apply whenever decisions are significant for safety.

ENSI's Mission Statement is the "master document" for all kinds of activities. The basic strategy for the implementation of the Mission Statement is the "Integrated Oversight" concept, which defines the fundamental safety functions to be met and the overriding safety goals. The major goals to be achieved are defined in a four-year cycle by the ENSI Board and documented in the Performance Mandate. Based on this mandate, a yearly Performance Agreement between the ENSI Board and ENSI's Executive Board sets up the goals (and the corresponding indicators) for one year. ENSI's Executive Board is reporting every quarter about the progress made with regard to the goals set. If necessary, corrective actions are defined by the ENSI Board in collaboration with ENSI's Executive Board. The entire process is documented in the main process "Management".

The fundamentals of the "Integrated Oversight" concept are an integral part of ENSI's Management System and as a consequence, the system is fully aligned with the organizational safety goals. The Management System includes all kind of activities including cultural aspects, safety and nuclear security aspects, quality, health, environment as well as legal requirements in an integrated manner.

4.3. THE MANAGEMENT SYSTEM

ENSI has established and implemented a process-oriented Management System, which is certified according to ISO 9001:2015. It comprises environmental management according to ISO 14001:2015 and health and safety management according to ISO 45001:2018, both without a certification. Beside this, ENSI features a laboratory for radiation measurement, which is accredited according to ISO 17025:2017. In addition, ENSI is accredited according to ISO 17020:2012 as an inspection body for radiation protection, radiation measurement and transport of radioactive materials. The system is assessed in a regular basis and continuously improved.

The management system of ENSI describes the organizational structure and core, support and management processes and responsibilities of the individuals in line with the organizational goals and objectives. ENSI implements its organizational changes by means of undertaking a project. The project description describes the entire process, steps to be taken and the questions to be considered till the effectiveness of the change is assessed.

A very systematic and organized internal decision-making process is applied for the decisions having a major impact on nuclear safety by involving all relevant staff members. The system for internal audits is well established

through which all the processes are audited at least once in every five years and external audits are also periodically conducted by concerned organizations.

ENSI observes the principles of proportionality (reasonableness) and expediency (appropriateness) in its activities to fulfil the requirement of the application of a graded approach. ENSI's Management System is tailored to take into account the safety significance, risk and complexity of the underlying activities of each process.

All the ENSI's Management System documents are stored in electronic form on a central server. There is an application called "Squirrel" that provides an easy process-oriented access to all Management System documents to all staff members. The rules for preparing, reviewing, revising and approving documents in ENSI's Management System are documented. The process owners are responsible for the control of the documents assigned to their process. There are rules for different document types. High level documents, e.g., main process descriptions, have to be approved by a delegate of ENSI's Executive Board. Documents, that are no longer used or being replaced, are stored in the archive for a period of at least 3 years.

The management system of ENSI is well documented, and has been developed and is applied using a graded approach.

4.4. MANAGEMENT OF RESOURCES

ENSI has a human resource strategy that includes the management of individual competencies and performance. According to this strategy, ENSI has the goal to be an attractive employer and to use efficient processes for recruiting staff in a timely manner. ENSI systematically plans its future need for qualified staff and it systematically monitors key figures such as employee turnover and absence from work.

ENSI launched several initiatives (such as a new recruitment concept, training and succession planning) in 2020 which take resource and competence requirements into account. A project "Training Concept on nuclear technology issues and regulatory law" was launched in the same year (see also Section 3.3). Currently, the competence requirement for leadership for all management levels are defined in the competence catalogue and additionally in the job specifications of leading staff, and the requirements with regard to technical and personal competencies of all members of the staff are defined in the individual job specifications. Requirements of competence are also discussed in the annual review process between line managers and employees. Training and professional development are considered through organizing in-service training courses, seminars; postgraduate studies or courses; coaching; individual development programs and others according to ENSI's Personnel Development Concept.

Although many instruments are operational and several projects have been completed or are in progress, it was observed that there is currently no systematic approach providing an overall view of staff competencies at ENSI or a corresponding tool for this which provides the necessary information for concise succession planning or personnel development programmes. ENSI considers that the determination of necessary resources and competences is one of its managerial challenges. ENSI has identified this issue as an area for improvement in the self-assessment report submitted to the IRRS team as ARM. The IRRS team supports ENSI's observation and encourages ENSI to establish the means which provide more and overall information of current competences of staff in order to systematically assess possible gaps to take further actions and to sustain the desired level of competence.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although many instruments are operational and several projects have been completed or are in progress, it was observed that there is currently no systematic approach providing an overall view of staff competencies at ENSI or a corresponding tool for this which provides the necessary information for concise succession planning or personnel development programmes.*	
(1)	**BASIS: GSR Part 2 Requirement 9 states that** *"Senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them."*
(2)	**BASIS: GSR Part 1 (Rev. 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".*
(3)	**BASIS: GSG-12 para 6.26. states that** *"The competences required by the regulatory body in order to fulfil its functions should be identified by means of a systematic analysis of competence needs based*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	on the regulatory body's function and processes. This should take place at periodic intervals, and when necessitated by substantial changes."
S2	**Suggestion: ENSI should consider establishing a systematic competence development framework to assess possible gaps to take further actions and to achieve and sustain the desired level of competence of the staff.**

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

The current system is process oriented and consists of 26 main processes arranged in four process groups including assessment of facilities, surveillance of operations, management processes and support processes. The former two groups made part of core processes and represent the main activities of ENSI to fulfil the mandate given by the legislation. Process activities are carried out according to process descriptions and further applicable documents. All documents are available to all employees through an electronic tool on a central server (Squirrel).

ENSI's Management System reflects qualification and oversight of the supply chain. ENSI may sign contracts with external experts for support in relation to its oversight activities. According to its management system, ENSI only concludes contracts with independent experts, subject to the conditions that the contracting experts must not work in a segment of an organisation which is overseen by ENSI and that the experts must not assess parts or systems of a nuclear installation, which were designed, built or assessed by themselves on behalf of supervised entities. These criteria do not rule out any other business relations between ENSI's experts and the supervised entities, e.g., research contracts or consulting (see suggestion in Section 3.4). Any expert advice is internally reviewed according to ENSI's quality management system.

4.6. CULTURE FOR SAFETY

The senior management of ENSI describes Safety Culture by integrating its organizational culture with its regulatory oversight of safety culture of the Swiss nuclear facilities. Specific topical issues including safety aspects are presented to all interested staff members in the frame of an event called "One Hour for Safety" held about ten times per year. Individual training and development plans support the line managers in fostering safety culture.

ENSI explicitly refrains from drawing a distinction between safety and nuclear security culture in its regulatory activities, although it does consider the specific requirements for nuclear security and safety. The themes of safety and nuclear security are dealt with under the generic term "safety culture". Instead of the term "safety culture of the regulatory authority", ENSI uses the term "oversight culture" which describes those aspects of the organizational culture of the regulatory authority that relate to the exercise of its core mission, i.e., in the case of ENSI, the oversight of Swiss nuclear facilities.

ENSI launched a broad-based process designed to scrutinize and improve its safety culture in 2012. The large-scale project involved all of the ENSI employees, and it was completed three years later in 2014 in three phases, the first two phases being the assessment phases and the third one was dedicated to the definition of actions for improvement in the safety culture of the organization. The findings obtained were converted into measures, which were implemented in the years to come.

Some key steps taken by ENSI to strengthen its safety culture are as follows:

- In order to achieve a common understanding of the key safety culture aspects within the organization, safety culture is explicitly addressed in the process "Management" which anchors the important safety culture issues such as regulatory basis, oversight practices, communication, improvement and decision-making.
- Fostering a strong safety culture is one of the tasks of all line managers and its implementation is discussed with the line managers in the annual performance reviews as well as in the reviews of the individual goals of each employee on a periodic basis.
- ENSI encourages its staff to adhere to cultural values and focus on their ability to work together constructively.
- Personal accountability of ENSI employees is referred to in ENSI's documents such as Mission Statement, ENSI's Code of Conduct and ENSI's Personnel Regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ENSI conducted a multi phased approach to developing its organizational safety culture along with its Oversight Culture using an interactive and iterative approach with the ENSI staff. Upon completion, the project was implemented through diverse means, including lectures, training courses, feedback training, and self-reflection activities, to achieve both broad and in-depth communication with the staff. Even though the project as such is over, the identified processes remain alive and continue to influence ENSI's performance in the future.*	
(1)	**BASIS: GSR Part 2 Requirement 14 states that** *"Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization".*
(2)	**BASIS: GSR Part 2 para 6.9. states that** *"Senior management shall ensure that self-assessment of leadership for safety and of safety culture includes assessment at all organizational levels and for all functions in the organization. Senior management shall ensure that such self-assessment makes use of recognized experts in the assessment of leadership and of safety culture."*
GP1	**Good Practice: ENSI's activities with regards to organizational safety and its oversight culture were found remarkable for effective development and continuous improvement of a culture of safety in the organization.**

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

ENSI monitors and assesses the effectiveness of its Management System by means of various instruments. Processes are monitored by the process owners through performance indicators. In addition, Management System documents are periodically reviewed in the framework of internal and external audits. Internal audits follow a yearly audit plan and are performed by internal auditors. External audits are carried out regularly by an external organisation which certifies ENSI's Management System to ISO-9001. The system as a whole is reviewed yearly in the framework of the Management Review to check its compliance with ENSI's goals and strategies. Furthermore, the management system is reviewed by the Executive Board yearly to make sure it is in line with goals and to define preventive or corrective actions whenever the conditions for work change. Finally, an external organisation (SQS Audit) regularly reviews the Management System (ISO 9001 certification).

4.8. SUMMARY

ENSI has established and implemented an integrated management system which clearly lays down processes, roles, responsibilities, procedures, measurable goals, strategies, plans and objectives. The management system is regularly reviewed, adapted and improved and it is aligned with ENSI's safety goals. The system, however, lacks a systematic competence development framework. ENSI management is aware of this fact and has been working on a plan to fulfil the long-term competence needs by achieving and sustaining the required level of competence in ENSI's employees.

ENSI efforts of establishing and continuously improving the culture of safety in the organization and the culture for oversight of the authorized parties is commendable and, therefore, can be regarded as a good practice.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The requirements governing the authorisation process associated with nuclear and radiation safety are established by the Nuclear Energy Act (NEA) of March 21, 2003 and the Radiological Protection Act (RPA) of March 22, 1991, adopted by the Federal Assembly of the Swiss Confederation. The Swiss Federal Council is authorised to regulate the authorisation procedure through secondary legislation instruments, including the Nuclear Energy Ordinance (NEO) of December 10, 2004 and the Radiological Protection Ordinance (RPO) of April 26, 2017.

The NEA and RPA require authorizations for all nuclear facilities and associated activities. The authorisation process encompasses all the stages of the lifetime of the nuclear facilities, i.e., siting, construction, operation and decommissioning or closure in case of a deep geological waste repository. Requirements and criteria for activities subject to mandatory licensing and for exemptions from the mandatory authorisation and supervision regime are included for example in the RPO. Requirements for exemption from the mandatory authorisation are also included in NEO Art. 61.

The legal system of Switzerland requires that several governmental bodies, predominantly part of the executive power, participate in the authorisation process, e.g. the Federal Council, the Federal Department of Environment, Transport, Energy and Communications (DETEC), the Federal Office of Energy (SFOE). At the same time, through NEO Art. 73, ENSI is legally empowered to review the documents submitted in the authorisation process. The expertise of ENSI covers all aspects of the authorisation framework except those related to environmental impact evaluation, spatial planning requirements, preservation of cultural heritage and the prescribed insurance cover in accordance with the Nuclear Energy Liability Act.

The Nuclear Energy Act provides for granting four types of authorisations covering nuclear safety, nuclear security and radiation protection: licences (a general licence covering among others the stage of siting, construction and operating licence), orders, permits and licences on operating personnel in nuclear facilities.

The authorisation procedure is the same irrespective of the type of the nuclear facility (e.g., Nuclear Power Plant (NPP), research reactor, radioactive waste facility, fuel storage facility or disposal facility), but is implemented in accordance with a graded approach.

According to Art. 12 of NEA, anyone intending to construct or operate a nuclear facility must obtain a “general licence” by the Swiss Federal Council, except for the cases where the intended facility is classified as having “low hazard potential”.

The general licence is associated with the decision of the state to construct a NPP on a specific site. The decision-making includes not only technical considerations, but also a significant political component. As a result, the decision making involves the Federal Council and also the Federal Assembly of the state, which is authorised to endorse the decision of the Federal Council. The procedure for the issuance of a general licence includes broad civil society engagement and debates through so-called “public consultation”. Such a decision could also be subject to a popular vote (referendum).

The construction and operating licences are granted by DETEC using approximately the same procedure. The list of the documentation to be submitted by the applicant together with the construction and operational licence application is specified in an appendix of NEO. Thus, an application for a construction licence includes, amongst others: a safety analysis report (SAR), an environmental impact assessment report, a report on compliance with the spatial planning requirements and a decommissioning plan or, in case of deep geological waste repositories a project for the monitoring period and a plan for closure. The application for an operating licence should be supported by a demonstration of compliance with the provisions established in the general licence and the construction licence, and with the relevant nuclear safety and security requirements. A Final Safety Analysis Report and the relevant technical documentation necessary for the operation, e.g., technical specifications, in-service inspection programme, ageing monitoring programme, security report, are also required.

As part of the authorisation procedure, DETEC and the Swiss Federal Council are empowered to issue orders imposing duties to the license holders related to specific activities such as decommissioning of a nuclear facility or closure of deep geological waste repository.

As an integral part of the authorisations of nuclear facilities and activities, permits are issued by ENSI within the framework of the existing licences and decommissioning/closure orders. The grounds for the issuance of such permits are established directly in the legislation or in the conditions attached to a licence or to the respective order. Thus, the licence or order conditions can specify the commissioning steps of a nuclear installation or

specific decommissioning activities where permits are required. In addition, permits are issued by ENSI for safety-related modifications that do not deviate significantly from the respective license or order.

According to NEA Art. 22 (2) "d" and NEO Art. 33, the license holders must carry out a systematic safety and security assessment, including the impact of the modifications to the installation. The risk assessment must incorporate an up-to-date plant specific probabilistic safety analysis (PSA).

The conduct of Periodic Safety Reviews (PSRs) is provided for in NEA Art. 22 (2) "e" and NEO Art. 34 (1). The holders of an operating licence for a NPP are obliged to carry out a comprehensive periodic safety review (PSR) every 10 years. General guidance in the conduct of a PSR is provided for in ENSI regulatory guide "Periodic Safety Reviews for Nuclear Power Plants". However, there is no such legal requirement that a PSR should be performed for the other nuclear facilities, such as facilities for management of radioactive waste and research reactors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *According to the legal framework (Art. 22 (2) p. "e" of the Nuclear Energy Act and Art. 34 (1) of the Nuclear Energy Ordinance) the holders of an operating licence are obliged to carry out comprehensive periodic safety reviews (PSR) for nuclear power plants every 10 years. There is no legal requirement that a PSR shall be required for the other nuclear facilities, such as facilities for management of radioactive waste and research reactors.*	
(1)	**BASIS: GSR Part 4 (Rev. 1) para 4.8. states that** *"The frequency at which the safety assessment shall be updated is related to the radiation risks associated with the facility or activity, and the extent to which changes are made to the facility or activity. As a minimum, the safety assessment shall be updated in the periodic safety review carried out at predefined intervals in accordance with regulatory requirements. Continuation of operation of such facilities or conduct of such activities is subject to being able to demonstrate in the reassessment, to the satisfaction of the operating organization and the regulatory body, that the safety measures in place remain adequate."*
(2)	**BASIS: SSR-3 para 4.25. states that** *"Systematic periodic safety reviews of the research reactor in accordance with the regulatory requirements shall be performed throughout its operating lifetime, with account taken of operating experience, the cumulative effects of ageing, applicable safety standards and safety information from all relevant sources. The operating organization shall verify by analysis, surveillance, testing and inspection that the physical state of the reactor facility, including experimental devices and facilities, is as described in the safety analysis report and other safety documents, and that the facility is commissioned and operated in accordance with safety requirements and the safety analysis and operational limits and conditions."*
(3)	**BASIS: GSR-5 Requirement 16 states that** *"The operator shall carry out periodic safety reviews and shall implement any safety upgrades required by the regulatory body following this review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility."*
R3	**Recommendation: The Government should establish provisions to ensure that all nuclear facilities will be subject to periodic safety reviews at predefined intervals, in accordance with a graded approach.**

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

The system of granting authorizations described above applies in its entirety to the NPPs.

According to NEA, the general licence specifies the license holder, the location and purpose of the installation, brief outline of the project and the maximum permissible exposure to radiation for people in the vicinity of the installation. The operating licence specifies the licence holder, the permitted reactor thermal output or capacity of the installation, the limits for release of radioactive substances into the environment, the measures for environmental surveillance, the safety, security, and emergency measures to be taken by the licence holder during the operation of the installation, and the activities that require a permit from ENSI prior to commencement of operation.

The content of the licenses is very general in nature and respectively the licenses are subject to amendment in only very limited cases. In practice the licenses are quite static and the authorisation process for the operational period of the NPPs is implemented through the permits issued by ENSI within its capacity as a regulatory

authority. The legal basis for the issuance of permits is different from that of licences, but the content of the permits is required to be in compliance with the licences and regulatory requirements.

According to Article 21 (2) of NEA, there is a possibility that the validity of the operating licence can be limited to a specific period of time, but in practice the licenses for the operation of the NPPs are issued without a time limit, which requires systematic control by ENSI. The licence holders are obliged to carry out inspections and systematic safety reviews, periodic safety reviews, long-term operation reviews and security evaluations throughout the entire service life of the facilities. ENSI reviews the safety analyses and assessment using an integrated oversight approach.

After the Fukushima Daiichi accident, the Swiss Government issued a ban on granting general licences for new NPPs. According to Art. 12a of the NEA in force since January 2018, the granting of general licenses for new NPPs is prohibited. Consequently, the authorisation procedure described above could be implemented now only for nuclear facilities other than NPPs.

For existing NPPs, Art. 106 of NEA stipulates that the nuclear facilities requiring a general licence which are already in operation may continue to be operated as long as no changes are made that require an amendment of the general licence in accordance with NEA Art. 65 (1). According to this article an amendment of the general licence is required

- for a change in the purpose or scope of activities of a nuclear installation that requires a general licence (excluding decommissioning or closure);
- for a comprehensive upgrading of a NPP in order to significantly extend its service life, in particular by replacing the reactor vessel.

In practice, so long as the results of the PSR continue to demonstrate safe operation, it is unlikely that there will be a need to amend the licences of the NPPs.

In summary, the legal framework for authorization of NPPs is in line with the IAEA requirements.

5.3. AUTHORIZATION OF RESEARCH REACTORS

In the Swiss legislation, the authorization process is the same, in principle, for any nuclear facility. There is only one operating research reactor in Switzerland which is a zero-power research reactor (CROCUS at EPF-Lausanne).

The Swiss authorization process cover all stages of the life cycle of a research reactor as required by SSR-3: site evaluation, design, construction, commissioning, operation, including utilization and modification, decommissioning, clearance from regulatory control.

The general requirements for the content of the licensing application are established in NEO Art. 23 (general licence), Art. 27 (construction licence), Art. 28 (operation licence) and Art. 45 (decommissioning order) as applicable for research reactors. According to Art. 20 of the NEA, the operation licence and the construction licence can be granted simultaneously if a final judgment on the safe operation of a facility can be made at the same time.

The application documents submitted by the licence holder are subject to review and assessment by ENSI with the support of external experts, if necessary. Specific requirements for the content of application documents, as well as certain aspects of safety, are defined in legislation and relevant guidelines, in accordance with a graded approach.

Art. 25 of the Ordinance on the Requirements for the Personnel of Nuclear Installations (VAPK) states that in research reactors, individual licences are required for reactor operators, reactor technicians, and reactor physicists. These licences are granted by the licence holder of the nuclear facility. ENSI reviews the list of competences and training programme of applicants and directly participates in an examination process. Each licence requires written consent from ENSI to be issued.

The permits required from ENSI within the framework of the construction licence (Art. 17 of the NEA) are specified in Art. 26 of the NEO for construction of structures, systems and components; within the framework of the operating licence (Art. 21 of the NEA) in Art. 29 of the NEO for stages of start-up prior to commencement of operation of the facility; and in Art. 40 of the NEO for modifications.

Overall, the licensing process for research reactors is in accordance with IAEA safety standards. However, there is no legal requirement that a periodic safety review shall be required for the research reactors (see IRRS team recommendation in Section 5.1).

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

In the Swiss legislation, the authorization process is the same for any nuclear facility, including deep geological waste repositories.

According to Art. 54 of NEO radioactive waste must be conditioned as quickly as possible using only ENSI approved procedures. Waste products must be suitable for transport storage and disposal in the future deep geological repository. For the assessment of the latter ENSI takes into account the statement of Nagra, the Agency for radioactive and spent fuel disposal.

With reference to deep geological waste repositories, as indicated in para. 1.7 of this Report, Nagra will submit an application for a general licence by 2024.

The documents that must be submitted in the application for a general licence are described in Articles 23 and 62 of NEO. Additional requirements for deep geological waste repositories are provided by Guideline ENSI-G03, recently updated in 2020.

Art. 37-41 of NEA and Art. 63-72 of NEO contain special provisions for deep geological waste repositories and includes requirements for construction, operation, a monitoring period and final closure. After the final closure, the licensee must submit documentation of the underground facility as built, filled and closed to the relevant Federal Department in accordance with Art. 71 of NEO.

Overall, the licensing process for waste management facilities is in accordance with IAEA safety standards. In the guideline ENSI-G08, a systematic safety assessment report for storage facilities is requested every 10 years. However, there is no legal requirement that a periodic safety review shall be required for waste management facilities (see IRRS team recommendation in Section 5.1).

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The operating license for nuclear facilities is issued by DETEC under NEA and covers activities involving handling of radiation sources necessary for or arising from the operation of the nuclear facility such as nuclear fuel, start-up sources or material contaminated with fission or activation products. It follows by RPO that such sources and activities do not need an additional license according to the RPA. Activities with radiation sources, not covered by the operating licence or by the decommissioning order under NEA, require a licence according to RPA issued by ENSI. ENSI for instance issues licenses for the handling of radioactive material (sources), operation of X/gamma-ray equipment, commercial production of radionuclides as well as the export (shipment) and/or import (receipt) and transport of radioactive materials (no nuclear material, no waste) from and to nuclear facilities. Such licences are limited to a period of ten years maximum, after which a renewal is necessary.

ENSI's responsibilities thus may entail regulatory core functions with respect to activities such as:

- Non-destructive materials testing with X-ray or gamma sources;
- Use of radiation sources for level measurements;
- Functional test and calibration of measuring instruments with radiation sources;
- Use of thoriated welding electrodes;
- Baggage screening, explosives analysis (Ni-63);
- Delegation of own staff as occupationally exposed in other facilities;
- Training of employees with open or sealed radiation sources;
- Production of radioisotopes for medical or industrial purposes;
- Operation of XRF equipment (X-ray fluorescence analysis).

Licences for the use of radiation sources outside a particular facility, e.g. radiography sources are issued by the FOPH. If a radiography source is used in a nuclear facility, ENSI accepts the licence issued by FOPH and fully relies on the judgments already made by FOPH. This issue is further discussed in Section 6.9 in the report.

According to RPO, the licensee shall maintain a register over radioactive sources and radiation generators in their possession. Each nuclear facility has such a register and is requested to send updated information to ENSI on a

yearly basis. The FOPH is the responsible body for the national register for high activity sealed sources, which also includes the high activity radioactive sources at the nuclear facilities. Currently ENSI does not have access to the national register, but there are plans to grant ENSI such access on a need-to-know basis. FOPH and ENSI apply the classification system for sealed radioactive sources in accordance with IAEA GSR Part 3 Schedule 2 and RS-G-1.9. ENSI also include sources below the criteria for high activity sources in the register when appropriate from a safety point of view.

There are legal provisions for clearance of radioactive materials in NEO and the RPO. ENSI provides detailed requirements in the guideline ENSI-B04 ("Clearance of Controlled and Supervised Areas and of Materials from Mandatory Licensing and Supervision"). This guideline has been issued jointly by ENSI, the FOPH and the SUVA and is in line with the requirements in IAEA GSR Part 3 Appendix 1 schedule 1.

The IRRS team concludes that the provisions for authorisation of radioactive sources and radiation generators in Switzerland are in line with the IAEA standards.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Articles 26 through 29 of NEA and Articles 41, 42 and 45 through 49 of NEO provide the requirements for a Decommissioning Order for nuclear facilities. NEA Article 27 requires the owner of a nuclear installation to submit the final decommissioning plan to the relevant competent authorities. The plan is then reviewed by ENSI in coordination with SFOE, SFOEN, FOPH, SECO, SUVA and relevant cantonal authorities. A public consultation is also conducted according to Art. 53 of NEA. The Federal Department of the Environment, Transport, Energy and Communications (DETEC) will issue the decommissioning order as the licensing authority per Article 28 of NEA and Article 46 of NEO and may include licence conditions to be fulfilled by the applicant.

In October 2013, the energy company BKW Energy Ltd decided to shut down Mühleberg NPP by the end of 2019. To ensure that there would be a decommissioning order in place when they ceased operation, BKW submitted the decommissioning plan for review in December 2015. Based on the assessments of ENSI and other competent authorities, DETEC issued the decommissioning order in June 2018. Mühleberg NPP is the first NPP to enter decommissioning in Switzerland.

Before Mühleberg NPP applied for decommissioning, an inter-institutional monitoring group was created including all Federal and Cantonal Authorities that would be involved in the licensing process. All the technical and legal aspects, as well as communication with the public were discussed and clarified during 2014 and 2015.

Mühleberg NPP ended operation in December 2019. After a transition period, it was declared in permanent shut down in September 2020. Upon this declaration, the decommissioning order became effective, and the operating license expired. Decommissioning activities including dismantling and decontamination have commenced and are scheduled to be completed in 2031, at which time a second order including the conventional demolition of buildings will be necessary to complete the decommissioning process by 2034. Given the relatively short ten-year expected duration of activities, an additional review of the decommissioning plan is not expected to be needed, unless significant changes occur at the site.

The IRRS team visited Mühleberg NPP accompanied by staff from ENSI. During the visit, the NPP staff presented the main steps carried out from the initial application for the decommissioning order to the present status of activities at site. During the site visit, the IRRS team observed effective communications between ENSI and the decommissioning organization. The IRRS team also met with representatives of the NPP and discussed the relationship between the site management and the regulators.

The IRRS team concluded that the anticipated dialogue and collaboration among all the Federal and Cantonal authorities involved in the decommissioning licensing process is a good performance. This helped all the institutions expedite the licensing process, including the ENSI review and assessment, which was concluded in just two and a half years.

5.7. AUTHORIZATION OF TRANSPORT

ENSI is the competent authority in Switzerland for issuing approvals according to para. 802 of the IAEA Transport Regulations SSR-6 as described in Art. 2 of the Federal Act on the Swiss Federal Nuclear Safety Inspectorate (ENSIG), in conjunction with the dangerous goods transport regulations in Switzerland (e.g. Ordinance for the Transport of Dangerous Goods by road (SDR), Art. 25(3)). ENSI approvals are mainly package design approvals and some shipment approvals, including shipments under special arrangement. ENSI has issued 3 to 4 approvals per year over the last 3 years which include package design approvals of Type B(M), -IF, -AF,

and -B(U)F according to para. 802(a)(v) and (vi), approval of fissile excepted material according to para. 802(a)(iii) and special arrangement approval and shipment approval according to para. 802(b) and (c) of SSR-6.

ENSI's management system provides procedures for transport approvals and templates for the appropriate approval certificates. For package design approvals, ENSI typically uses the validation procedure in compliance with para. 840 of SSR-6. Structure and content of ENSI approval certificates are consistent with the applicable requirements of SSR-6.

In addition to approvals under SSR-6, ENSI also issues licenses for the transport of radioactive material from and to nuclear facilities in accordance with RPO, art. 11(2)(d), except transport of radioactive waste and nuclear material for which SFOE issues licenses relying on the technical expertise of ENSI. ENSI takes the applicable provisions of the IAEA Transport Regulations SSR-6 into account during the authorization procedure.

The authorization of transport based on the approvals issued by ENSI, as described above, is in compliance with the requirements of the Transport Regulations SSR-6.

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

Swiss regulations apply the concept of exposure situations recommended by ICRP and IAEA and occupational exposure as well as occupationally exposed persons are defined in those regulations. Pursuant to Art. 9 RPO; the deployment of occupationally exposed persons at one's own or at another enterprise in Switzerland or abroad is subject to mandatory licensing.

Apart from certain distinct situations, occupationally exposed persons are generally defined as: a) persons who in the course of their occupational activities or training may incur exposure which exceeds a dose limit for members of the public; or b) persons who at their workplace are subject to radon exposure and may thereby accumulate an effective dose of more than 10 mSv per year.

In order to obtain an operating licence for a nuclear facility the applicant must:

- appoint radiation protection experts, technicians and controllers who require recognized radiation protection training;
- provide technical, organizational and personal radiation protection measures;
- monitor workplaces and occupational exposure;
- appoint an approved dosimetry service provider; and
- establish a radiation protection programme (RPP) to limit and optimize occupational exposure, following the guideline for Operational Documentation as a general description of the organization and management of radiation protection in a nuclear facility.

The operating licence for a nuclear facility as well as other authorizations for radiation sources activities cover all occupational exposures from sources and activities that are necessary for operation of the facility or that originate from it.

Hence, under the RPA, for nuclear facilities, ENSI for instance issues licenses for the handling of radioactive material (sources), operation of X/gamma-ray equipment, commercial production of radionuclides as well as the export (shipment) and/or import (receipt) and transport of radioactive materials (no nuclear material, no waste) from and to nuclear facilities. Otherwise, the FOPH is the licensing authority. ENSI's responsibilities thus may entail regulatory core functions with respect to activities such as shown in the bullet list in Section 5.5.

In addition, under the RPA, ENSI also issues licenses for the delegation of personnel. If a licensee employs occupationally exposed persons at another facility in Switzerland or abroad, an additional licence is required. For this purpose, the licensee (or applicant) has to appoint a radiation protection expert, who has to ensure compliance with the annual dose limits by controlling the prior individual dose history and setting appropriate dose quotas. The FOPH is the licensing authority for the deployment of personnel in third-party companies.

Occupational exposure of emergency personnel is regulated under the RPA and RPO, which includes requirements on effective measures for the protection of emergency workers, resources, instructions and training as well as reference levels, as prerequisites for obtaining and maintaining authorization.

Finally, ENSI is responsible for the authorization of occupational exposure to radon at workplaces in nuclear facilities. As a consequence of the revision of the RPO and the dosimetry ordinance, nuclear facilities with radon-prone workplaces must ensure that measurements are conducted and if the reference level of 1,000 Bq/m3 is

exceeded, the annual radon-related effective dose to exposed workers must be determined. If the effective dose to a person at the workplace exceeds 10 mSv/year, the worker is considered to be occupationally exposed and is consequently subject to personal dosimetry, while the licensee is subject to a mandatory licence. Measures must first be taken to reduce the effective dose (RPO Art. 167, Para. 2). Only after the effective dose of the person is still above 10 mSv/year despite the measures, the person is considered as occupationally exposed (RPO Art. 167, para. 3) and must be dose monitored.

In summary, the legal framework for authorization of occupational exposure is based on both the NEA, NEO, RPA and RPO as well as FOPH directives such as the Federal Ordinance for the Prevention of Accidents and Occupational Diseases - and ENSI guidelines such as the ENSI-G12 on "Radiation Protection in Nuclear Installations" and ENSI-G09 on "Operational Documentation".

The IRRS team concludes that ENSI effectively complies with the requirements on authorization of occupational exposure.

5.9. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

According to the Swiss regulations, the concept of exposure situations as per IAEA Safety Standards including public exposure as per defined in the regulations. The dose limits for the public are stated in RPO and are in accordance with the IAEA standards. In RPO specific limits are prescribed for direct radiation and for activity concentrations in air and water in the vicinity of the nuclear facility. Discharge limits are set in the operational licence according to the NEA for nuclear facilities or in the DETEC's decommissioning order for facilities under decommissioning. For installations with both nuclear and non-nuclear facilities such as the PSI, the discharge limits are set in an order jointly issued by ENSI and FOPH. The discharge limits are based on the nuclear specific dose constraint provided by ENSI for each nuclear facility. The dose constraint is set in nuclear facility specific regulations issued by ENSI "Regulation for the release for radioactive substances and the monitoring of radioactivity and direct radiation in the environment of facility X".

It follows by Art.191 in the RPO that FOPH is responsible for the monitoring of ionizing radiation and the radioactivity in the environment and ENSI is responsible for additionally monitor ionising radiation and radioactivity in the vicinity of nuclear facilities.

This regulation defines the source related environmental monitoring in the vicinity of the facility and the specific measurements to be performed by the facility, ENSI, FOPH, and other laboratories. The licensee is responsible for monitoring the emissions from the facility, however according to the regulation ENSI as well as FOPH takes control samples as part of their inspections for comparison.

The legal framework for authorization of public exposure is based on NEA, NEO, RPA and RPO and a number of ENSI guidelines and regulations issued under an ENSI order and is well in line with IAEA safety standards.

5.10. SUMMARY

The Swiss legislation on nuclear energy and radiation protection requires authorizations for all nuclear facilities and activities unless explicitly exempted on the basis of their safety significance. On primary legislation level the legal requirements for the authorization process are established in Switzerland by the NEA and the RPA. The secondary legislation level consists of ordinances, the most important of which are the NEO and the RPO. The legal basis covers the whole life cycle of the nuclear facilities and activities. The authorization regime is well structured and ensures transparency and consistency in the decision making.

The IRRS team concludes that the anticipated dialogue and collaboration among all the Federal and Cantonal authorities involved in the decommissioning licensing process is a good performance.

For further enhancement of safety, the IRRS team recommends the Government to establish provisions to ensure that all nuclear facilities will be subject to periodic safety reviews at predefined intervals, in accordance with a graded approach.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The Swiss legal framework for nuclear safety designates ENSI as the organization responsible for the regulatory review and assessment of nuclear facilities and activities. ENSI performs regulatory oversight of nuclear power plants, research reactors, transport of nuclear material, decommissioning and radioactive waste management, use of radioactive sources and other activities, which support the licensing and permitting process.

The national legislation, acts, ordinances, guidelines authorisation basis and authorisation conditions state the requirements for performing regulatory review and assessment. The regulatory requirements are applied in a graded manner commensurate with the risk of the facility or activity.

ENSI's management system defines the regulatory review and assessment processes for safety-related aspects in all stages throughout the lifetime of nuclear facilities and regulated activities. The management system also includes associated procedures and supporting electronic tools that enable a systematic and comprehensive conduct of review and assessments.

ENSI verifies that the licensees implement systematic safety reviews, periodic safety reviews (PSR), long-term operation reviews and security evaluations throughout the entire service life of the installation. ENSI performs a systematic assessment of event analyses, inspection results, operator licensing reviews, safety-indicator data and information in the periodic licensee reports on an annual basis, as part of an integrated oversight approach for assessing nuclear safety of nuclear facilities.

The IRRS team concludes that ENSI has effectively established and implemented its management processes on regulatory review and assessment.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

ENSI employs approximately 150 staff members. More than 100 of those employees perform technical functions including the conduct of regulatory review and assessment, and inspection activities across four departments. ENSI specialists cover seventeen technical areas including, Civil Engineering, Electrical Engineering, Mechanical Engineering, Decommissioning, System Engineering, Site Inspection, Deterministic Analysis, Human & Organization Factors, PSA & Accident Management, Reactor Core, Occupational Radiation Protection, Nuclear & Cyber Security, Accident Consequence & Emergency Preparedness, Radiation Measurement, Transport & Predisposal, Geology, and Disposal & Analysis. Each area has specific core competence requirements in order to execute the tasks within their areas of responsibility.

ENSI developed and maintains a comprehensive training programme for building and maintaining the required staff competencies. ENSI leverages academic institutions, learning centres, research and development, and on-the-job training as mechanisms for implementing their training programme. ENSI is launching a knowledge management project that systematically covers all the technical areas related to the performance of regulatory review and assessment.

ENSI has contracts and agreements with external technical support organizations (TSO) and experts in order to obtain external technical supports as necessary to support its regulatory functions when there are not sufficient competence or resources within the organization. ENSI's outsourcing strategy outlines requirements for independent and periodic evaluation of performance and independence within the contracts for external providers to prevent conflict of interest.

The IRRS team conducted visits and interviews on issues related to facilities and activities, as well as occupational and public exposure. The IRRS team concluded from content and examples given in interviews with licensees, ENSI inspectors and ENSI senior staff that ENSI could further improve the training of its staff in order to apply a more consistent graded approach in the review and assessment of non-NPP nuclear facilities. Such training should especially focus on the practical application of recent updates of ENSI-guidelines and publication of the new ENSI-G23 for the purpose of better addressing the graded approach in nuclear facilities other than NPPs. The application of proportionality is explicitly established in ENSI's permitting process, and the ENSI-G23 guideline was recently published for non-NPP in order to take the graded approach into account.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team concluded from content and examples given in interviews with licensees, ENSI inspectors and ENSI senior staff that ENSI could further improve the training of its staff in order to apply a more consistent graded approach in the review and assessment of non-NPP nuclear facilities.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para 4.62. states that** *"The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach"*
(2)	**BASIS: GSR Part 3 para 2.31. states that** *"The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation"*
(3)	**BASIS: GSR Part 3 para 2.32. states that** *"The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety".*
S3	**Suggestion: ENSI should consider, in the training of staff, to better address the graded approach in review and assessment of non-NPP nuclear facilities, in order to improve the application of relevant ENSI guidance material.**

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The legislation and regulatory framework for nuclear facilities and activities are well established in Switzerland. The Nuclear Energy Act, the Nuclear Energy Ordinance, the Radiological Protection Act, the Radiological Protection Ordinance and associated ENSI guidelines establish the main legal basis for regulatory review and assessment.

ENSI has issued approximately 40 regulatory guidelines to enable the implementation of regulatory requirements which cover all aspects of the lifetime of nuclear facilities and activities, i.e. siting, design, construction, commissioning, operation, decommissioning, closure, nuclear waste management, transport, disposal, radiation protection and emergency preparedness.

The IRRS team concludes that ENSI has effectively established its bases for regulatory review and assessment.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

ENSI verifies the completeness of the safety assessment applications, as well as their compliance with regulatory requirements. The licensee is required to perform independent verification of any safety analysis performed by external experts, prior to submitting the assessment to ENSI for regulatory review and assessment.

ENSI performs the regulatory review using a variety of mechanisms including employing the support of external experts. ENSI engages in technical meetings and multiple interactions with the licensees in order to discuss applications. ENSI performs confirmatory calculations and analyses to verify the adequacy of submissions that have a significant impact on safety. ENSI may perform inspections of nuclear facilities in order to verify specific assumptions in the plant models.

The performance of regulatory review and assessment is a core process in ENSI's management system. The implementation of the process is monitored and evaluated through self-assessments, internal independent audits and international peer reviews. ENSI also monitors regulatory reviews and assessment performed by external TSOs or experts.

The IRRS team concludes that ENSI has effectively monitored and evaluated the performance of regulatory review and assessment.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

ENSI performs regulatory oversight of the three operating nuclear power plants (NPP) in Switzerland based on the existing regulations, ENSI Guidelines and management procedures. ENSI reviews activities conducted by the licensees, such as maintenance, in-service inspection and functional testing, systematic safety assessments, ageing

management, modifications or backfitting of components and plant documents that are important to safety, and periodic safety reviews (PSR). Licensees of NPPs conduct PSRs every ten years and include additional demonstrations of safety for long term operation (LTO) beyond the fourth operating decade.

The NEO requires the NPPs to implement Deterministic Safety Status Analysis (DSSA), which focus on protection against design basis accidents and selected beyond design basis accidents. The licensee must demonstrate that the relevant plant and core-specific parameters remain within safe limits and comply with the required technical criteria as well as the individual dose criteria for the public. ENSI's review process also includes DBA analyses using appropriate computer codes and ENSI's own plant models to independently verify licensees' assessment.

The NEO requires the development and use of a full-scope PSA for all relevant operating modes in NPPs. All NPPs have been performing plant-specific Level 1 and Level 2 studies, including internal and external events (e.g. fire, flooding, earthquakes, aircraft crashes and high winds), and update their PSAs every 10 years as part of the PSR. At least once every five years, PSA models are updated to reflect plant modifications and the availability of additional reliability data. Additional updates of the PSA are required, if plant modifications have a significant impact on the risk or relevant hazard assumptions (like earthquake) changes. ENSI implements regulatory review using its own independent and plant-specific PSA models.

Operating NPPs have implemented significant safety improvements based on safety evaluation as well as national and international experiences, such as the Fukushima Daiichi accident, and state-of-the-art practices. The term "state of the art of backfitting technology" was introduced to indicate that all backfitting measures that are technologically feasible and appropriate must be considered and implemented.

For significant backfitting and modifications, the licensees are required to submit appropriate safety analyses and related documentation in support of permit applications in four steps: concept, design, installation and operation. The following evidence are required before any such permit can be granted: the suitability of manufacturing process and of the assembly and commissioning processes, compliance with safety limits, details of the dedicated start-up tests as required, procedure for periodic inspections and audits, and finally probabilistic evaluation in respect of the impact on the risk according to the plant-specific PSA (e.g. plant core damage frequency). This evidence aims to ensure that each modification or backfitting measure conforms to previously approved safety requirements, and the relevant safety margins and operational limits are maintained.

The IRRS team discussed with ENSI about regulatory policy and requirements on continuous safety improvement in Switzerland. The IRRS team was provided with information demonstrating that ENSI promotes continuous safety improvements at NPPs. The IRRS team visited Beznau NPP accompanied by staff from ENSI. During a plant walkdown the most important backfits performed in the past were presented. The IRRS team considers the role of ENSI to implement the regulatory policy and the associated requirements as a good performance.

The IRRS team concludes that ENSI is effectively complying with the requirements for regulatory review and assessment of nuclear power plants.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

There is only one operating research reactor in Switzerland, which is a zero-power research reactor. The CROCUS at EPF Lausanne is a nuclear facility with a very low hazard potential as demonstrated by safety analysis.

ENSI's review and assessment process is the same for any nuclear facility including research reactors.

ENSI acknowledges that safety review and assessments are performed in a graded approach that is commensurate with the magnitude of the possible radiation risks arising from the facility or activity, during the operational phase. Periodic safety reviews are not required for research reactors in the Swiss legislation, as recommended by IAEA SSR-3 "Safety of Research Reactors" (Requirement 5).

Swiss legislation requires the systematic safety assessments of all nuclear facilities, including research reactors, according to Art. 22 of the NEA, and Art. 33 of the NEO. Specific requirements for the content of the assessments, as well as certain aspects of safety, are defined in legislation and relevant guidelines, in accordance with a graded approach.

Articles 37 of the NEO requires that licence holders submit an annual report to ENSI, for the purpose of assessing the status and operation of the installation, which contains a summary and an assessment of operations and safety, operating state of the installation, site-related changes, organisational structure and personnel, radiation protection, radioactive waste management, radiological situation and findings from observation of current state

of the art in science and technology. It contains results of systematic safety assessments and reports on the status of pending matters with ENSI, events and findings, modifications and maintenance operations. The structure and content of the annual report are defined in guideline ENSI-B02 “Periodic Reporting by the Nuclear Installations”. Systematic assessment of the research reactor, which is performed by the licensee in accordance with the Art 22 of NEA, Art. 33 of NEO is carried out individually in each topical area. The annual report includes a summary of all key areas, such as: modifications, events, etc. However, it doesn’t provide an overall view of all the assessed topics in an integrated manner (see IRRS team recommendation in Section 5.1).

Based on duties of competent authorities, defined in the Art. 72 of the NEA, ENSI evaluates applications and makes assessments on compliance with safety requirements and regulatory guidelines using the results of the evaluation in future regulatory activities, particular in planning and conducting inspections. ENSI has the capability to involve external experts for the regulatory review and assessment process of research reactor but does not exercise this option in practice. ENSI is fully staffed with its own qualified personnel for review and assessment of research reactor.

The IRRS team concludes that ENSI is compliant with the requirements for review and assessment of research reactors.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

All conditioning, storage and disposal facilities are regulated as nuclear facilities. The NEA and the corresponding NEO require the owners of all nuclear facilities to review and assess the safety of these facilities systematically and regularly under the supervision of ENSI. The operational spent fuel pools (SFP) placed at the NPP sites are regulated under the NPPs’ licensing conditions.

ENSI Guideline G09 “Operational Documentation” provides the requirements to be met by documentation for predisposal facilities during the specified operation phases. According to ENSI G09, the content and detail of the safety report for predisposal facilities shall be based on IAEA Safety Standard GSG-3 while for interim storage facilities (including spent fuel in dry storage) the WENRA Waste and Spent Fuel Storage Safety Reference Levels should be used.

Periodic safety reviews every 10 years is formally required by NEA for NPPs. No similar requirements are given in the legislation for nuclear facilities other than NPPs. In the ENSI Guideline G08, a systematic safety assessment report for storage facilities is requested every 10 years. (See IRRS team recommendation in the Chapter 5.1.)

For a disposal facility, a safety assessment addressing the period after closure (long-term safety) is required at each licensing step. ENSI Guideline G03 provides the requirements on long-term safety for the design and planning of disposal facilities, and compliance to these requirements needs to be verified as part of ENSI regulatory reviews.

The IRRS team concludes that ENSI is complying with the requirements for regulatory review and assessment of waste management facilities.

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The licencing process under NEA for nuclear facilities comprises review and assessment of safety activities with radiation sources necessary for or arising from the operation of the nuclear facility. For nuclear facilities, the discharge limits specified in the operational licence is based on the source related dose constraint laid down in ENSI-G15 (“Radiation protection objectives for nuclear facilities”). The established dose constraint is 0.3 mSv/year for a representative person and are imposed in order to protect the general public. The licences do not set dose constraints for the public to facilitate the optimisation of protection for the public. ENSI has established a target value for the discharges based on good practices used in similar facilities based on UNSCEAR data.

Further activities with radiation sources that are not covered by the NEA licence require a licence under the RPA (see Chapter 5). Applications for granting or renewing RPA licences must be submitted to ENSI including the necessary documents.

Regulatory reviews and assessments, of the relevant information concerning radiation sources and activities not covered by the NEA licence are conducted for all stages of the lifetime of a nuclear installation based on the Swiss radiation protection legislation.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

According to the Swiss legislation, the owner of a nuclear installation is obliged to decommission its facility (Art. 26 NEA) and shall submit the final decommissioning plan no later than two years after the final shutdown (guideline ENSI-G17).

However, in the case of Mühleberg NPP, BKW, the owner of the NPP, submitted the final decommissioning plan for review in December 2015, 4 years before the end of operation in order to ensure that there would be a legally binding decommissioning order in place when they ceased power operation in 2019.

Immediate dismantling is the preferred strategy for decommissioning, however, as indicated in the ENSI Guideline G-17, a deferred dismantling may also be acceptable, provided that there is justification in the decommissioning application.

The application documents are reviewed by ENSI and the Guideline G17 "Decommissioning of Nuclear Installations" provides all the required content for the final decommissioning plan including a safety analysis report for each phase of the decommissioning process.

A PSR is foreseen only in the case of deferred dismantling.

The IRRS team concludes that ENSI is complying with the requirements for regulatory review and assessment of decommissioning activities.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

In order to prepare the evaluation report as basis for an approval, ENSI reviews and assesses applications for approvals to check regulatory compliance of applications. Within ENSI's management system, guidance is available regarding the procedures and the requirements for such reviews and assessments for package design approvals as well as shipment approvals. If necessary, external support is acquired, consistent with the conditions as outlined in the ENSI management system, for particular activities including shielding analysis, thermal analysis, and for inspecting and reviewing manufacturing of packagings, general quality assurance aspects and the qualification of specific materials. The results of the review and assessments are finally documented in an evaluation report, for which appropriate templates are used as specified in the management system.

Regarding the review and assessment of applications for package designs it was found that not all areas are covered by specific internal guidelines. While such a specific internal guideline exists to review and assess criticality safety, specific guidance does not exist for the areas of mechanical, thermal and radiation safety, which are of equivalent safety significance. This leads to the suggestion below.

According to para. 308 of SSR-6, it is required that the relevant competent authority shall arrange for periodic assessments of the radiation doses to persons involved in transport activities of radioactive material to ensure that the system of protection and safety complies with the IAEA Basic Safety Standards. It was found that ENSI has not arranged such a dose assessment so far. Based on a graded approach, this is currently acceptable due to the relatively small number and specific types of transports within ENSI's domain. The need for such a dose assessment may arise in the future if the transport praxis may change due to increasing numbers and/or locally concentrated shipments of radioactive material (e.g. transports in conjunction with increased decommissioning activities or locally concentrated transports to a central waste repository).

The review of transport regulations and related guides is integrated into the overall system of ENSI for review and revision of regulations and guides based on ENSI's active participation in the review and revision cycles of the IAEA regarding the IAEA Transport Regulations SSR-6 and its related Safety Guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ENSI has implemented internal guidance on procedures for review and assessment of package designs which also include specific guidance for the review and assessment of criticality safety of package design but not for review and assessment of mechanical, thermal and radiation safety of the package design.*	
(1)	**BASIS: GSG-13 para 3.191. states that** *"The regulatory body should provide internal guidance for its own staff on the procedures to be followed in the review and assessment process and on the safety objectives to be met. Internal guidance on specific topics for review and assessment should also be provided, as necessary."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: TS-G-1.5 para. 4.79. states that** *"Irrespective of which organization carries out the design assessment, the assessor should be aware of the basic purpose of the Transport Regulations and should give very careful consideration to any aspect of the design, however obscure, that could adversely affect:* *a) The effective containment of the radioactive material;* *b) The effective control of any radiation emitted from the package;* *c) Maintenance of a subcritical condition for any fissile material;* *d) The adequate dissipation of heat generated within the package..."*
S4	**Suggestion: ENSI should consider revising its internal guidance for review and assessments of package designs to include guidance for the assessment of mechanical, thermal and radiation safety together with the existing guidance on criticality safety in a consistent manner.**

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

The regulatory framework for regulatory review and assessment for occupational exposure is defined in the NEA, NEO, RPA, RPO and ENSI Guidelines. ENSI reviews the Radiation Protection Programme (RPP) as part of the documents necessary to support the application for an operating license and verifies the implementation of procedures and provision defined in the RPP by evaluation of relevant reports from the licensee – and by inspections.

For the special cases of planned annual outages, ENSI reviews the resulting occupational exposure and, if these exceed target dose values, the licensee must provide an explanation for the cause and propose measures for improvement for ENSI to review as well.

ENSI inspects and regularly reviews the monitoring programmes and approved dosimetry services, verifies the compliance of an authorized (or notified) activity, including the deviation from dose target values by inspection and by evaluation of relevant reports from the licensee, as well as the transferred individual dose data for plausibility before they are transmitted to the Central Dose Registry.

The IRRS team concludes that ENSI is complying with the requirements for regulatory review and assessment of occupational exposure.

6.9. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

For nuclear facilities, the discharge limits specified in the operational licence are based on the source related dose constraint laid down in ENSI guidelines. The licensees are obliged to optimise the radiation protection for the public according to the RPO as well as ENSI guidelines. The licensees monitor their radioactive discharges according to the NEA, NEO, RPO and these requirements are specified in a nuclear facility specific order "Regulation for the release of radioactive substances and the monitoring of radioactivity and direct radiation to the environment for facility X".

The radiation dose to the public for planned exposure situations is calculated using a methodology prescribed in ENSI guidelines. The methodology being used seems to be very simple and conservative, but it does not represent the state of art concerning methodologies used for this purpose. It needs to be revised taking into account new technical knowledge and improvements, new parameters such as dose conversation factors, transfer factors or changes in exposure pathways. ENSI has identified the issue and initiated a revision two years ago, with limited progress. It is important for public trust that the methods used to calculate radiation doses to the public are based on the latest technical and scientific knowledge.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The methodology for the calculation of the radiation dose to the public for planned exposure situations according to ENSI-G14 guideline does not take into account current technical and scientific knowledge and is not updated due to changes in parameters or conditions that could affect the exposure of members of the public.*	
(1)	**BASIS: GSR Part 3 para 3.118. states that** *"The government or the regulatory body shall establish the responsibilities of registrants and licensees, of suppliers, and of providers of consumer products in relation to the application of requirements for public exposure in planned exposure situations."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 3 para 3.126. states that** *"Registrants and licensees… in applying the principle of optimization of protection and safety in the design, planning, operation and decommissioning of a source… shall take into account: (a) Possible changes in any conditions that could affect exposure of members of the public, such as changes in the characteristics and use of the source, changes in environmental dispersion conditions, changes in exposure pathways or changes in values of parameters used for the determination of the representative person;…(c) Possible buildup and accumulation in the environment of radioactive substances from discharges during the lifetime of the source; (d) Uncertainties in the assessment of doses, especially uncertainties in contributions to doses if the source and the representative person are separated in space or in time."*
(3)	**BASIS: GSR Part 3 para 3.137. states that** *"Registrants and licensees shall, as appropriate… (g) Verify the adequacy of the assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts."*
S5	**Suggestion: ENSI should consider expediting the revision of the guidelines concerning the methodology for calculation of the radiation dose to the representative person used for the assessment of the dose to the public for planned exposure situations.**

6.10. SUMMARY

The legal basis and management processes for the Swiss regulatory review and assessment of nuclear facilities and activities have been well established. ENSI is fully committed to performing comprehensive and systematic review and assessment which meets the expectations of the IAEA safety standards for regulatory review and assessment, and support licensing, certification and compliance verification as a part of the regulatory oversight programme.

The IRRS team identified some opportunities for improvement in areas such as ENSI's policies and procedures for applying a graded approach for the core regulatory processes pertaining to non-NPP nuclear facilities, the internal guidance for review and assessment of mechanical, thermal and radiation safety of the package design, the methodology for the calculation of radiation doses to the public taking into account new technical knowledge and improvements.

The IRRS team considers the role of ENSI to implement the regulatory policy and the associated requirements for continued safety improvement at NPPs as a good performance.

7. INSPECTION

7.1. GENERIC ISSUES

According to the Nuclear Energy Act (SR 732.1) [NEA], Art. 72, para. 1, the regulatory authorities shall ensure that licence holders meet their obligations in accordance with the provisions of the Act. Articles 72 and 73 of the NEA empower ENSI to monitor the compliance with legislation and regulatory requirements using inspections.

The NEA further gives ENSI inspectors the right to enter all sites of nuclear facilities, buildings and installations without prior notification and inspect all relevant activities and records. ENSI maintains a qualified and competent staff of inspectors who perform both planned and reactive inspections in all nuclear facilities using a graded approach and in different phases of the lifetime of a nuclear facility. ENSI inspections also cover the transport of nuclear materials.

Inspection methods applied by ENSI include examination and evaluation of procedures, records and documentation, surveillance and interviewing of personnel, as well as the possibility to take samples and perform measurements. The results of ENSI's inspections are rated according to their safety significance and documented in inspection reports. The majority of ENSI staff members are inspectors (76) that perform about 450 to 500 inspections per year. Several of these inspections are performed by multi-disciplinary teams, covering different areas of competences. Inspections are an important tool of ENSI's Integrated Oversight approach.

ENSI collaborates with other authorities in the areas of common interests. For example, there is collaboration with the occupational health and chemical safety authorities to exchange information and findings on these areas at nuclear power plants. A memorandum of understanding has been signed with SUVA concerning inspection for conventional risks. Because the cantonal organizations in Switzerland are responsible for fire protection, ENSI inspections on fire protection are normally conducted in cooperation with the cantons. In the area of safeguards the responsible authority is the Federal Office of Energy, which also conducts inspections in the area. ENSI inspections in the areas of transport of radioactive materials involve broad cooperation with FOPH, SUVA and local and federal security organizations. In addition to ENSI, the Swiss Association of Technical Inspections (SVTI) department of nuclear inspectorate inspects the manufacturing, installation and maintenance of safety relevant components. Tasks of SVTI are defined in ENSI guidelines. ENSI oversees the activities and performance of SVTI by regular reporting, meetings and by following the correspondence between SVTI and the licensees.

Policy Issue: Counterfeit, Fraudulent, and Suspect Items (CFSI)

Swiss legislation requires the use of verified high quality processes, materials and techniques in nuclear power plants. Vendors, suppliers and nuclear power plants must verify the quality of items procured for performing safety-related functions. Verification activities include extensive inspections of an item's critical physical characteristics and the associated performance testing. These activities aim to confirm, with reasonable assurance, that items will perform their intended safety functions as required. ENSI evaluates CFSI occurrences to determine whether there are any implications on the Swiss nuclear power plants. ENSI commissions a technical support organization (TSO) to monitor the construction of safety-classified mechanical components and structures. However, ENSI recognizes the need to further improve the systematic monitoring by third parties for other components, such as electrical equipment, spare parts and small components.

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

- Current regulatory instruments for proactively detecting and preventing CFSI cases;
- IRRS team members experience with CFSI cases.

The policy discussion highlighted the following key items:

- Several countries emphasized the importance of strengthening the regulatory requirements applicable to the procurement of safety-related components including by a systematic reporting to the regulatory body for CFSI occurrences;
- Regulatory bodies should implement a strong inspection programme in this area that should include the review of CFSI related procedures and documentation, as well as routine and targeted inspections of licensee activities;
- Regulatory bodies should improve the knowledge and skills of the inspectors regarding the inspection of suppliers and manufactures, including the development of competencies in the assessment of quality

assurance programmes. A regulatory body may also choose to contract external inspection organizations that have the specific competence required for investigating CFSI issues;

- Regulatory bodies should implement arrangements for sharing relevant CFSI information collected from the licensees, detected during regulatory inspections, and received from the international community;
- Regulatory bodies should implement approaches for collecting and investigating alerts from whistle blowers;
- Some countries developed CFSI classification levels for the installation of items, in accordance with the associated hazard level, in order to determine the appropriate surveillance level;
- Several countries emphasized the importance for regulatory bodies and licensees of being vigilant on CFSI matter.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

The inspection process for nuclear power plants includes planning and preparation of the inspections, conduct and reporting of inspections, and allocation of responsibilities for the inspection process. The preparation, execution, reporting and follow up activities of inspections are guided by the ENSI management system described in HPB0260, including Inspection Planning (IAU9000), Inspection Preparation (IAU9001), Conducting Inspections (IAU9002), Inspection Reports (IAU9003), and Team Inspections (IAU9004). Inspections are based on the Basic Inspection Programme (BIP) and are conducted by specialist inspectors as well as site inspectors, who are generalists and perform mainly unannounced inspections focused on normal plant operation and safety related outage activities. All inspectors are trained to do inspections, and inspectors recruited to ENSI after 2009 have gone through a formal qualification.

About half of ENSI inspectors received their initial qualification twelve or more years ago. To mitigate the loss of institutional knowledge that would result if a large number of experienced staff were to depart over a short period of time, the ENSI Board recently decided to allow expanding the turnover period for inspectors from periods of one year to periods from two to three years to allow for additional knowledge transfer to maintain a sufficient pool of competent inspection staff. The IRRS team considers this a good performance for maintaining competences of inspection staff, as also described in Section 3.3 of this report. However, ENSI still faces a challenge in recruiting caused by the reduction in nuclear talent pool available resulting from the decision to phase out of nuclear power in Switzerland (see Recommendation in Section 1.8 of this report).

Inspection findings at NPPS are used as inputs to ENSI's systematic safety assessment process. In the systematic safety assessment, the performance of the plant as well as the operator organisation is assessed within the framework of defence in depth. Annually ENSI performs a holistic assessment of the performance of each nuclear power plant to inform the development of the next year of inspections at each facility, using a graded approach. In addition to the planned inspections assigned from the BIP during the annual assessment, ENSI also performs reactive inspections to gather additional information about events or conditions at NPPs. The decision of whether to perform a reactive inspection and the resources to devote to the effort is not controlled by a documented process in ENSI's management system and is conducted on an ad hoc basis.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *When ENSI becomes aware of events or conditions at a nuclear facility that may warrant a reactive inspection to gather additional information, the determination for the timing and level of resources for the reactive inspection is made based on professional judgement.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections, both announced and unannounced."*
(2)	**BASIS: GSG-13 para 3.244. states that** *"Reactive inspections, by individuals or teams, are usually initiated by the regulatory body in response to an unexpected, unplanned situation or incident in order to assess its significance, the implications for safety and the adequacy of corrective actions…. A pre-established, graded approach to responding to special circumstances will assist in determining the appropriate level of resources for use in reactive inspections."*
S6	**Suggestion: ENSI should consider developing a set of documented criteria based on a graded approach for use in decision-making for the appropriate level of reactive inspection response for special circumstances.**

In 2012, ENSI initiated a project to assess the safety culture within their own organization, termed "Oversight Culture," which was based on the recognition that the strategy and culture of the regulator by its nature will influence the culture of the regulated organizations. The goal of the project was to create an ongoing reflection process within ENSI about its own safety culture and how it could provide a role model for the regulated organizations as a positive motivation for safety responsibility as well as how it impacts the regulated organizations' safety and safety culture through the way it exercises its oversight work. This effort is described further in Section 4.6 of this report. In parallel, ENSI developed a report explaining its understanding of safety culture and its oversight approach to safety culture as an instrument for transparency towards the licensees as well as for promoting a common understanding within ENSI itself and developing further its approach to both oversee and strengthen the safety cultures of the regulated organizations. ENSI's oversight approach of safety culture is based on the assumption that safety culture cannot be "measured" in the strict sense of the word, but rather can only be "appraised" in a qualitative way, if at all. ENSI does not make overall judgements/statements about the safety culture of the licensees as a whole.

The Human Organisational Factors section of ENSI holds a dialogue on safety culture with the senior leadership teams and safety culture specialists of the NPP licensees every three years as part of ENSI's oversight of safety culture at nuclear facilities. The dialog is a focus group -style facilitated discussion on an aspect of safety culture, with the intention of promoting an awareness among the senior leaders of their demonstrated attitudes towards safety culture and the potential impacts to the members of the organizations they lead. ENSI has received positive feedback from NPP licensees about the self-reflection gained through the focus groups and the related exchange on safety culture issues within their organisation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Every three years the ENSI Human Factors Organization holds a dialogue on safety culture with the senior leadership teams and safety culture specialists of the NPP licensees. This focus group is a facilitated discussion of a topic related to safety culture, with the intention of promoting self-awareness among the senior leaders of their demonstrated attitudes towards safety culture and the resulting potential impacts to the members of the organizations they lead.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 5 states that** *"The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance."*
GP2	**Good Practice: The safety culture focus groups are an effective tool for proactively engaging the senior management of NPP operators to promote self-awareness of their impact as leaders on the safety culture of their organizations.**

7.3. INSPECTION OF RESEARCH REACTORS

The process described in Section 7.2 for nuclear power plants is implemented to the applicable extent for research reactors. Utilizing the BIP, ENSI establishes annual inspection programmes for all nuclear facilities, including research reactors. ENSI has nominated facility inspectors for research reactors who conduct inspections based on the results of regulatory review and assessment of licensee reports (e.g., observations from previous inspections, SAR, annual safety assessment report, assessment of modifications, event reports) to ensure compliance with applicable regulations.

The inspection process for research reactors typically involves inspectors from the Transportation and Predisposal Section of ENSI – which is the lead organization for oversight of research reactors – and the Reactor Core Section. Inspectors from other ENSI departments may also be involved depending on the planned inspection topics.

Consistent with a graded approach, the number of inspections and other oversight activities performed at research reactors is less than that performed at nuclear power plants due to lower risk of radioactive products to people and the environment. In a typical year, ENSI performs two or three inspections at research reactors. The results of these inspections are used to inform future oversight activities.

The IRRS team concludes that ENSI is complying with the requirements on inspection of research reactors.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

In accordance with a graded approach, only few percent of total ENSI inspections are focused on radioactive waste (RW) management facilities, including spent fuel dry interim storage facilities. This results in approximately 10-15 inspections per year. Focus areas for these inspections in waste management facilities are spent fuel stored in dry casks, quality of produced waste packages, record keeping, and licensee's inspection programme for packages in interim storage.

All ENSI inspectors can perform inspections of waste management facilities if their respective field of expertise is applicable (e.g., radiation protection, management systems, RW management, engineering, etc.). For each facility there is an assigned facility inspector.

The IRRS team concludes that ENSI is complying with the requirements on inspection of waste management facilities.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Inspection of radiation sources at nuclear facilities is included in ENSI's accredited inspection programme for nuclear facilities and is carried out each fifth year according to this programme. Many of the specialised inspections conducted by ENSI also include review of the protection and safety concerning radiation sources as part of the inspection activity. There are detailed checklists available for the inspection of radiation sources to support such inspections. In a typical year the control of radiation sources and activities are fully encompassed by about 30 different inspections.

In addition, the use of mobile sources used by external workers (e.g., radiography sources) which are licenced by FOPH but used within a nuclear facility fall under the supervision and control of ENSI.

The IRRS team concludes that ENSI is complying with the requirements on inspection of radiation sources, facilities and activities.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

ENSI created a decommissioning section with currently a total of four staff members (planned to be five people by 2022) to focus on decommissioning licensing processes and inspections. One of the staff members is the assigned site inspector for Mühleberg NPP, which is the only NPP in decommissioning stage.

The preparation, execution, reporting and follow up activities of inspections are indicated in the ENSI management systems. Inspection programmes for nuclear facilities in decommissioning, given the permanent changes in these installations, is not included in ENSI Basic Inspection Programme. The decommissioning inspection programme is established annually using a graded approach and according to the planned activities of the installations

Because a lot of the preparatory measures for decommissioning and of post-operational activities at Mühleberg were performed during the transition period (from December 2019 end of operation to September 2020 permanent shut down) and during this first period of dismantling activities under the decommissioning order (see para. 5.6 of Module 5), 105 inspections have been performed by ENSI. These inspections were often performed by multidisciplinary ENSI inspection teams from different ENSI Departments, covering different topics (e.g., radiation protection, civil engineering, RW management, electric systems, etc.) as well as with external authorities in the area of occupational safety and health.

The IRRS team concludes that ENSI is complying with the requirements on inspection of decommissioning activities.

7.7. INSPECTION OF TRANSPORT

Transport related inspections are performed by ENSI itself and the technical expert organisation SVTI on behalf of ENSI within its responsibility over transport of radioactive material to and from the nuclear facilities, at the nuclear facility sites, before the transport takes place or after its arrival. There are programmed and, if appropriate, reactive inspections. Inspections are usually announced and rarely unannounced due to the short-term planning of transport activities and the need to obtain a permit from ENSI for shipment activities. Transport inspections cover:

- consignment and reception of packages;
- handling, loading and storage of packages within facilities;

- preparation and maintenance of documentation;
- procedures related to the transport of radioactive material; and
- manufacturing of packagings.

Additional inspections related to the transport of radioactive material are performed by:

- FOPH and SUVA in facilities and companies within the industrial, medical and research area;
- Cantonal police on public roads;
- Border police for international transport;
- Other competent authorities on cargo activities at the airports, on inland waterway and railway.

Because many authorities are performing inspections related to the transport of radioactive material, an annual meeting takes place to exchange inspection results and to ensure compliance assurance.

After each inspection, results are communicated to the inspected organisation to enable feedback and comments are recorded. Finally, ENSI issues a comprehensive inspection report to the inspected organisation. Findings are forwarded to the overall ENSI enforcement process.

ENSI inspectors for the transport of radioactive material have specific training before they are appointed. Part of the training is a one-week course at the level of a safety advisor for the transport of class 7 material. The inspectors need to pass a three hour exam at the end of the course to be appointed as ENSI transport inspectors, additional internal trainings as well as attending at transport inspections at each nuclear facility are necessary. Because ENSI is an officially certified inspection body for the transport of class 7 material, there are annual training courses for appointed inspectors reflecting inspection experiences and addressing specific subjects to support their daily work.

Procedures and checklists for transport inspections are available within ENSI's management system. These checklists are related to inspection activities on marking and labelling of packages, transport documents, radiation categories and limits for dose rates and contamination. Checklists for other inspection areas with equivalent significance like maintenance of packages, loading and unloading operations as well as audits of consignors, carriers and consignees are not part of the management system. Guidance for such checklists is provided in TS-G-1.5 (paras. 4.72-4.74 and 4.93) and even more specific and in consistency with TS.G.1.5 in the "Compliance Inspection Guide, Issue 1, February 2015", published by the European Association of Competent Authorities for Transport of Radioactive Material (EACA). The IRRS team suggests to review and revise the inspection instructions of ENSI such that all relevant inspection areas are covered in consistency with TS-G-1.5 and other related international guidelines, such as the EACA Compliance Inspection Guide.

Consistent with the requirement of para. 302 in SSR-6, ENSI inspects radiation protection programmes (RPP) for carriers. As an example, an RPP of a carrier was provided which was fully consistent with the elements of an RPP as outlined in TS-G-1.3. ENSI is encouraged to use this example as basis for the inspection of RPPs of other carriers in a consistent manner.

Regarding radiation protection programmes for nuclear facilities in its function as a consignor or consignee for transport it was found that documents on procedures and activities concerning consigning and receiving of packages are in place which do also address the elements of a radiation protection programme as outlined in TS-G-1.3. As an administrative matter, ENSI should request the nuclear facilities to bundle such RPP relevant documents directly or by reference to them into a single document under the heading "Radiation Protection Programme".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ENSI has implemented inspection checklists for transport which are focusing on marking and labelling of packages, transport documents, radiation categories and limits for dose rate and contamination. Other areas as e.g. maintenance of packages, loading and unloading operations, as well as audits of the consignor, carrier and consignee which include inspection activities as described in paras. 4.72-4.74 of TS-G-1.5 for consignors and carriers are not covered.*	
(1)	**BASIS: GSG-13, para. 3.220. states that** *"Regulatory inspection is performed to make an independent check on the authorized party and the state of the facility or activity, and to provide confidence that the authorized party is in compliance with the safety objectives prescribed or approved by the regulatory body. …"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSG-13, para. 3.262. states that** *"The regulatory body should issue internal guidance for its inspectors on performing regulatory inspections in order to ensure a consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise. Each inspector should be given adequate training in following this guidance."*
(3)	**BASIS: TS-G-1.5 paras. 4.72.-4.74. state that** *"the competent authority should verify the following… by which a comprehensive list of inspection items for consignors and carriers is provided."*
S7	**Suggestion: ENSI should consider reviewing and revising its inspection instructions for transport in compliance with applicable inspection activities, such as described in TS-G-1.5.**

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

Inspections concerning occupational exposure are closely integrated in ENSI´s programme for inspection of radiation sources, facilities, and activities. Inspections of these activities comprise the review of radiation protection plans, including determination of occupation-specific protection measures and monitoring, as well as the verification of how protection measures and monitoring are implemented. Inspections of occupational exposure cover the efficiency and optimisation of radiation protection measures as well as the adequacy of monitoring provisions.

For the inspection of dosimetry service providers, ENSI assigns an external competent service (Institut de Radiophysique [IRA], University of Lausanne) to review the approved dosimetry service providers of registrants and licensees. This review has to be done every five years in accordance with Article 67 of the RPO, as part of a joint inspection by an IRA expert and ENSI in order to maintain the recognition of the dosimetry service . Additionally, ENSI regularly inspects the dosimetry monitoring programmes and dosimetry services of nuclear facilities. ENSI furthermore inspects the dose data reported from licensee and dosimetry services as well as the recording and reporting of licensee and dosimetry services (document IAU9215).

Although ENSI is not the responsible regulatory authority with respect to exposure from natural radiation, ENSI is the responsible authority with respect to occupational exposure to radon in nuclear facilities. Following a screening of nuclear facilities, two research reactor facilities required installation of ventilation systems as mitigating measures to ensure radon levels are kept below the reference value. In 2021, ENSI will conduct so-called focused inspections in all three NPPs to ensure compliance with occupational exposure controls for radon as decided at the annual ENSI integrated oversight meeting.

The IRRS team concludes that ENSI is complying with the requirements on inspection of occupational exposure.

7.9. INSPECTION OF PUBLIC EXPOSURE

Inspections concerning public exposure are integrated in ENSI´s overarching programme for inspections. Specific inspections on releases of radioactive substances are performed every three months years, according to the programme.

The nuclear facility specific regulations issued by ENSI for the periodic monitoring programme contains control of samples, e.g., of air filters in the exhaust stack and environmental samples in the vicinity of the facility. According to the programme, ENSI together with the FOPH take samples and compare their measuring results. The results are documented in ENSI inspection reports. There are well-defined trigger levels for when specific actions have to be taken as a result of the environmental measurements.

The IRRS team concludes that ENSI is complying with the requirements on inspection of public radiation exposure.

7.10. SUMMARY

The IRRS team considers that the inspection process as described in the ENSI management system is being followed for nuclear facilities, transport, and the protection of exposed workers, the public and the environment during the use of radioactive materials.

ENSI organises safety culture focus groups for the licensees every three years with the intention of promoting safety culture awareness among the senior leaders. The IRRS team considers these focus groups as an effective

tool for proactively engaging the senior management of NPP operators to promote self-awareness of their impact as leaders on the safety culture of their organizations. This is considered a Good Practice.

The ENSI Board recently decided to allow expanding the turnover period for inspectors from periods of one year to periods from two to three years to allow for additional knowledge transfer to maintain a sufficient pool of competent inspection staff. The IRRS team considers this a good performance for maintaining competences of inspection staff.

The IRRS team encourages ENSI to consider developing a set of documented criteria to aid in determining the timing and resources appropriate for reactive inspections, and to consider revising its inspection instructions for transport to be in compliance with applicable inspection activities, such as described in TS-G-1.5.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The comprehensive enforcement regime in place is legally based on articles 72 and 73 of the Nuclear Energy Act (NEA) that notably specifies that "the regulatory authorities shall order all necessary and reasonable measures aimed at preserving nuclear safety and security", which means that the response should be commensurate with safety significance. The enforcement powers of ENSI are defined by of article 72 of the NEA, in particular immediate measures to be taken in case of immediate threat (para3).

To fulfil the requirements of article 184 of the Radiological Protection Ordinance, ENSI, FOPH and SUVA meet twice per year for the coordination of their enforcement activities and to carry out joint inspections.

According to article 101 para. 6 of the NEA, ENSI "may call on third parties to assist with the enforcement of this Act." Concerning pressurized equipment of nuclear facilities, ENSI has delegated inspection, assessment and enforcement tasks to SVTI which is an accredited inspection body in accordance with ISO/IEC 17020. The enforcement measures of SVTI are actually very limited, involving only informal orders on site with information provided to ENSI. The contract frame for providing assistances requires independence and confidentiality from SVTI.

The enforcement power of ENSI is defined in the legislation and the right to appeal is taken into account in the enforcement regime. ENSI does not specify in its management system the decision-making process for prosecution or the interface between ENSI and the prosecutor. As licensees usually comply with the orders, ENSI almost never faces situations such as difficulties to enter facilities for inspection or to obtain documentation or shutting down a facility or revocation of an authorization. This could be considered as an indicator of the efficiency of existing enforcement measures and a culture of safety awareness among the licensees.

The Swiss legal framework does consider the prosecution of a licensee under restrictive conditions only, amongst others if felonies and misdemeanours cannot be attributed to a specific individual. Prosecution procedures are therefore mostly limited to individuals. The NEA gives precision on fines and/or term of imprisonment for individuals if a safety system is made inoperable either wilfully or unintentionally. Penalties imposed on the license holder are only an exceptional instrument of enforcement in the Swiss legal framework, although article 22 para 1 of the NEA places the responsibility for the safety of the installation and its operation on the license holder. Considering that the mistakes or errors of individuals are typically strongly linked to the work organization and conditions, the IRRS team considers this position as inappropriate. Prosecution of individuals for mistakes that were not done wilfully could dissuade individuals from reporting events or significant issues for fear of prosecution, which would result in problems going unrecognized and prevent learning from events. To avoid this negative impact on safety and safety culture, the possibility of the licensee to be hold responsible and prosecuted in lieu of an individual should be introduced in the legal framework.

A parliament postulate concerning the issue of "just culture" was adopted in 2020 by the parliament: "The Federal Council is charged with determining how to introduce the just culture or positive culture of error as a general principle in Swiss law applying to aviation, health and other high security areas." A working group with representatives of branches with a high hazard potential including ENSI has been formed. It will prepare a report in 2022 for the Federal Council.

The IRRS team concludes that the Government should improve the legal framework to allow prosecution of licensees instead of only individuals.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Swiss legal framework only considers prosecution of individuals and not of the authorized parties. Prosecution of individuals may have negative impacts on problem identification and resolution and safety culture.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 30 states that** *"The regulatory body shall implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization"*
(2)	**BASIS: GSR Part 1 (Rev. 1) para 4.57. states that** *"The authorized party shall be held accountable for remedying non compliances, for performing a thorough investigation in accordance with an agreed timetable and for taking all the measures that are necessary to prevent recurrence of the non-compliances."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSG-13 para 3.305. states that** *"Experience in some States suggests that imposing penalties on the authorized party rather than on individual workers is preferable as it is more likely to lead to improved safety performance."*
R4	**Recommendation: The Government should ensure that the legal framework - given the importance of safety culture – also allows prosecution of a licensee instead of an individual.**

8.2. ENFORCEMENT IMPLEMENTATIONS

Non-conformances and violations of regulations are identified by the ENSI inspectors from the processes inspection, event processing, expert reports, permits and the elapsed deadline of a plant task, etc. ENSI has defined different possibilities of enforcement depending on the significance of the non-compliance according to GSR Part 1 (Rev. 1) Paragraph 4.58.

Formal meetings with the managers of the entity above the licensee is sometimes carried out, but it is not considered by ENSI as an enforcement measure in spite of its admitted efficacy. ENSI can issue either informal orders or formal orders that are in the end both binding. Formal orders can originate from an authorization process, oversight process, reported events or review and assessment conclusions. In most cases, this procedure is sufficient to resolve the safety issue. It is implemented by the reviewers, the inspectors and their supervisor for validation, and is addressed on a very general level in the inspection process in the management system. The inspectors are trained on the enforcement process mainly by mentoring.

In principle, ENSI can require an authorized party to restrict or suspend the operation of specified facilities or activities and to take any further action necessary to restore an adequate level of safety. As formal orders are usually sufficient either to restore an adequate level of safety or to lead the authorized party to make the decision, to restrict or to suspend its own activities, ENSI has not detailed in the management system this process that could lead to a facility shutdown or a license withdrawal and the associated criteria as these requirements are largely already defined in Art. 43 and 44 NEO. The decision of enforcement or prosecution would be made on a case-by-case basis.

Article 72 para 3 of the NEA gives the possibility to ENSI to "impose immediate measures that deviate from the issued license or ruling." The objectives of these measures are mentioned, however specific measures that could be taken by the inspectors are not defined. The enforcement process must be applied whenever either a deviation or a non-compliance with safety requirements or conditions specified in the license is detected by ENSI, upon inspection or after event. During inspections, there is a possibility to impose measures for situations that require immediate actions. The procedures dealing with the role of the inspectors (IAU9002) mention the possibility of enforcement by the inspectors as immediate actions and contain a reference to the enforcement procedure (HPB0340).However, it does not give detailed guidance on how to take corrective action if there is an imminent likelihood of safety significant events. ENSI has already identified these weaknesses and the revision of enforcement and inspection procedures is in progress.

The IRRS team concludes that the provisions for enforcement are included in the legal framework, but should be described in the management system notably in the inspection and in enforcement procedures which are being revised.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The legal framework addresses the immediate actions inspectors are authorized to take if there is an imminent likelihood of safety significant events. However, in the management system of ENSI the related provisions are on a very general level.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para 4.58. states that** *"The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary. On-site inspectors, if any, shall be authorized to take corrective action if there is an imminent likelihood of safety significant events."*
(2)	**BASIS: GSR Part 1 (Rev. 1) para 4.15. states that** *"The management system of the regulatory body has three purposes:* *(1) To ensure that the responsibilities assigned to the regulatory body are properly discharged; …"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSR Part 2 Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organization's goals without compromising safety."*
(4)	**BASIS: GSR Part 2 para 4.28 states that** *"Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation."*
(5)	**BASIS: GSG-13 para 3.311. states that** *"The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions, which should be documented in internal guidance."*
R5	**Recommendation: ENSI should update its enforcement procedures in relation to immediate corrective actions inspectors are authorized to take if there is an imminent likelihood of safety significant events.**

8.3. SUMMARY

A comprehensive enforcement regime is in place in the legal framework. As prosecution is mostly limited to individuals only, the IRRS team recommends updating the legal framework to enable prosecution of licensees instead of individuals.

The parliament adopted in 2020 a postulate concerning the issue of "just culture"; a working group involving ENSI has been established accordingly. It will issue a report in 2022.

ENSI's management system is not complete concerning the description of the role of the inspectors in the enforcement process, including the actions they should be authorized to take for corrective action if there is an imminent likelihood of safety significant events. IRRS team recommends developing ENSI's management system to address the issue. ENSI has already started to work on this.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The Swiss legislative and regulatory framework for nuclear and radiation safety includes the Federal Constitution of the Swiss Confederation, Acts, Ordinances, and associated Guidelines. The Acts and Ordinances outline the regulatory requirements, and the associated guidelines outline detailed supporting information that enables compliance with the regulatory requirements.

The Nuclear Energy Act (NEA), the Nuclear Energy Ordinance (NEO), the Radiological Protection Act (RPA) and the Radiological Protection Ordinance (RPO) govern the regulation of civilian uses of nuclear materials and facilities. The NEA and NEO establish principles and requirements, respectively, for ensuring nuclear safety and security, and licensing nuclear facilities and activities. RPA and RPO establish the basic principles and requirements, respectively, for the radiation safety of activities, installations, events and situations that may involve ionizing radiation hazards and establishes an emergency response organization.

The NEA defines the role of ENSI in the regulatory process and authorizes ENSI to issue guidelines. ENSI develops guidelines in accordance with an Act and/or an Ordinance and categorizes them into the areas of assessment of facilities, surveillance of operations, and general requirements. ENSI guidelines contain comprehensive information for enabling the appropriate and uniform implementation of regulatory requirements. ENSI may accept an alternative approach for meeting the regulatory requirements if it provides an equivalent or higher level of protection and safety or nuclear security. ENSI may also adopt internationally recognized standards that perform the same function as a guideline.

ENSI's management system includes the process description HPB0140, entitled Regulatory Basis Process, for developing, establishing and modifying regulations and guidelines. ENSI may adopt an internationally recognized standard in the area of protection and safety or nuclear security by referencing it in a guideline, referencing it in a regulatory letter, or by adopting the standard in place of a guideline. HPB-0140 does not outline the process for adopting internationally recognized standards in place of guidelines.

The Regulatory Basis Process includes a transparent consultation process that strives to ensure that the intent and impact of a guideline is fully understood by all stakeholders. However, this process does not include a requirement for consultation with interested parties on the adoption of internationally recognized standards in place of guidelines.

ENSI publishes a complete set of guidelines on their website in order to notify the public of the established regulatory framework. However, the Regulatory Basis Process does not include requirements for notifying interested parties, including the public, when an internationally recognized standard is adopted in place of a guideline.

For cases where ENSI adopts internationally recognized standards into the regulatory framework in place of guidelines, ENSI should clarify whether the practice is still applicable to the current regulatory model. If the practice is still applicable, ENSI should update their process to provide sufficient clarity.

ENSI revises the regulatory guidelines every 10 years, or if there are relevant modifications of international and technical standards, and relevant regulatory operating experience. The Regulatory Basis Process and AAU1192 entitled Specification Guideline, outlines the mechanism and criteria for revising the guidelines. However, AAU1192 does not include the consideration of relevant international operating experience as a criterion for revising the guidelines.

Overall, ENSI has a well-established regulatory framework that enables the effective regulatory oversight of nuclear facilities in Switzerland.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *AAU1192 Specification Guideline outlines the criteria for determining the need to modify regulatory guidelines; however, it does not include criteria for considering relevant international operating experience and lessons learned.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSG-13 para 3.66. states that** *"Experience from implementing the regulations should be examined and any problems or difficulties should be duly considered. The status of relevant requirements should also be examined in the light of new safety related developments. The possible effects of frequent changes in regulations and guides on the stability of the regulatory system should be taken into account. The reasons for revising regulations may include: changes in legislation; changes in the organization, responsibilities, policies or procedures of the regulatory body; experience gained by the regulatory body in the authorization process; feedback of information and experience from events, as well as from relevant national and international good practices; technological advances; and the need to improve or eliminate any impractical, misleading, unenforceable or otherwise inadequate regulations."*
S8	**Suggestion: ENSI should consider updating the process for revising guidelines to include relevant international operating experience as a criterion for recommending modifications to guidelines during the annual review.**
Observation: *HPB-0140 Regulatory Basis defines the process for the establishment and modification of regulations, standards and guides. ENSI may adopt an internationally recognized standard by referencing it in a guideline, referencing it in a regulatory letter, or by adopting the standard instead of creating a guideline. HPB-0140 does not provide sufficient clarity regarding the adoption of a standard instead of creating a guideline, and as a result, does not specify requirements for notifying the public or for public consultation.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 34 states that** *"The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available."*
(2)	**BASIS: GSR Part 1 (Rev. 1) para 4.61. states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience."*
R6	**Recommendation: In cases where ENSI adopts international standards in place of creating a guideline, ENSI should clarify the process for the adoption of the standard, and notifying and facilitating consultation with interested parties.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

The Swiss Nuclear Power Plants (NPPs) are regulated in accordance with the NEA, NEO, RPA, RPO and associated guidelines. ENSI has established and maintains a comprehensive set of guidelines that cover key areas such as fundamental safety functions, defence in depth, reliability, design basis, design extension and postulated initiating events, operational limits and conditions, personnel qualification and training, accident management, operating procedures, maintenance, testing, surveillance and inspection, and monitoring and control of activities performed by vendors, contractors and suppliers. ENSI guidelines also cover radiation protection of workers and the public.

ENSI guidelines are routinely revised in accordance with the description of the Regulatory Basis Process, HPB-0140. The ENSI guideline, ENSI-G07 entitled Organization of the Nuclear Installation, specifies requirements for the licensees' management system and is currently based on the IAEA safety standards GS-R-3, "The Management System for Facilities and Activities". However, the IAEA standard GSR Part 2 Leadership and Management for Safety, superseded the IAEA standard, GS-R-3. ENSI is currently drafting a new version of ENSI-G07 that aligns with GSR Part 2.

In addition, ENSI-G07, outlines the requirements for procurement and intelligent customer capability. The nuclear sector has experienced notable challenges in the area of counterfeit, fraudulent and suspect items (CFSI). Guideline ENSI-G07 refers to CFSI but does not include sufficient guidance to reflect the experience gained in the area.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Guideline, ENSI-G07 "Organization of the Nuclear Installation", which specifies requirements for the licensees' management system is based on the IAEA safety standards GS-R-3, "The Management System for Facilities and Activities", which has been superseded by GSR Part 2"Leadership and Management for Safety". There is an ongoing ENSI activity to update ENSI-G07 to bring it in line with GSR Part 2.* *ENSI-G07 refers to licensee requirements for procurement and intelligent customer capability; however, it does not include sufficient requirements taking into account the experience gained in the CFSI area.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
(2)	**BASIS: GSR Part 2** *in its entirety*
S9	**Suggestion: ENSI should consider completing the revision of guideline ENSI-G07 to be aligned with GSR Part 2 Safety Requirements and to strengthen the criteria for the systematic management of CFSI.**

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

The legal framework for research reactors in Switzerland is based on the NEA, NEO, RPA, RPO and a series of ordinances. In accordance with the graded approach, there are no regulations and guidelines developed specifically for research reactors; however, the regulatory requirements for research reactors are included in the guidelines for other nuclear facilities. ENSI has the mandate to issue the necessary guidelines concerning specific protection and safety or nuclear security aspects for research reactors.

ENSI has established and maintains a comprehensive set of guidelines for all nuclear facilities including research reactors, that covers key areas such as fundamental safety objective, fundamental safety functions, defence in depth, design, site evaluation, commissioning, operational safety, operating instructions and procedures, operational limits and conditions (OLC), verification of safety, maintenance, calibration, testing, surveillance and inspection, control over experimental devices and experiment personnel, competence of personnel, radiation protection, emergency preparedness and response, radioactive waste management and decommissioning, management system, and safety and nuclear security interface.

The IRRS team considers that generally, the Swiss legislation complies with the requirements of IAEA SSR-3 "Safety of Research Reactors", with the exception of the guideline, ENSI-G07 "Organisation of nuclear installations", which should be updated to comply with GSR Part 2. The relevant IRRS team suggestion is listed in Chapter 9.2 of Module 9.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Several ENSI Guidelines regulate radioactive waste conditioning and storage, dry interim storage of spent fuel as well as disposal of radioactive waste and spent nuclear fuel.

The conditioning of radioactive waste requires an approval by ENSI. The requirements on the conditioning process, the waste package type and its documentation are defined broadly in the NEO and in detail in the Regulatory Guideline ENSI-B05 (2018).

The need to provide requirements, concerning the design of storage facilities, is identified in the ENSI IRRS Action Plan. Therefore, ENSI developed the new guideline ENSI-G23 ("Design Principles for other Nuclear Installations"), which entered into force in October 2021.

The operation of interim storage facilities for radioactive waste, including spent nuclear fuel, is regulated in the new guideline ENSI-B17 "Operation of Interim Storage Facilities for Radioactive Waste" (2020), which supersedes the operational chapters of former guideline ENSI-G04.

The guideline ENSI-G05 "Transport and Storage Casks for Interim Storage" applies to the design, manufacture and use of dual-purpose casks. The licensees have applied the requirements in ENSI-G05 to the manufacturing of dual-purpose casks. The revised ENSI-G05 entered into force in October 2021.

Furthermore, in order to address ageing issues of loaded dual purpose casks in long term dry storage, ENSI published in 2018 a guidance document on ageing management of spent fuel in dry storage/dual purpose casks.

The specific design principles for deep geological repositories and the requirements for the safety case are provided in Guideline ENSI-G03 "Deep Geological Repositories" (2020), that has recently been revised to address the progress in the site selection and licensing process of the foreseen deep geological waste repository.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The legal framework for radiation protection in Switzerland is based on the RPA, RPO and a series of departmental ordinances and contains the fundamental principles of radiation protection concerning justification, optimisation and dose limitations. The FOPH also issues advisory material, so-called directives, with relevant provisions on occupational exposure, for instance a directive of the FOPH was developed in collaboration with ENSI and SUVA with requirements for the security of high-activity sealed sources, as well as, directive R-05-01 on the Protection of Occupationally Exposed Pregnant Females, which implements relevant requirements of the IAEA safety standards.

ENSI has the mandate to issue the necessary guidelines concerning safety and protection for radiation sources and activities in nuclear facilities. The guideline ENSI-G12 on Radiation Protection in Nuclear Installations, issued in September 2021, sets the overarching requirements related to radiation protection. Additional examples of ENSI guidelines relevant for radiation sources and activities in nuclear facilities are the ENSI-A08 Source term analysis, ENSI-B04 Exemption/Clearance, ENSI-G14 Calculation of radiation exposure in the vicinity due to emissions of radioactive substances from nuclear facilities and ENSI-G15 Radiation protection objectives for nuclear facilities. The ENSI-G14 concerning the methodologies for assessment of radiation doses to the public was issued in 2008 and has not been revised since. This is further developed in section 6.9 of this report.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

Guideline ENSI-G17 on Decommissioning of nuclear facilities, 2014, provides requirements concerning protection and safety for the decommissioning and the application documents for decommissioning. Guideline ENSI-G17 contains requirements on the content of the documentation to be delivered to the competent authority upon reaching the final status defined in the decommissioning order (final report). Additional requirements on operational documentation and records management are given in the Guideline ENSI-G09. No specific requirements addressing the collection and retention of relevant records and reports or for preserving information are given, notwithstanding that Art. 41 NEO, point 5, requests ENSI to specify detailed requirements in its guidelines on documentation and archiving of information. It is important that future generations can fully understand and reconstruct the operation history as well as the decommissioning of a former nuclear installation.

It was noted that, under Action 6 of the ENSI IRRS Action Plan, ENSI-G17 will be revised in order to address the issue of the transition period. In this regard, the IRRS team recommended that ENSI guidelines should include requirements for the collection and retention of records and reports relevant to decommissioning, and for preserving information about the activities that have been conducted at the site.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The decommissioning regulations do not establish requirements for the collection and retention of records and reports relevant to decommissioning, and for preserving information about the activities that have been conducted at the site.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para.4.63. states that** *"The regulatory body shall make provision for establishing and maintaining the following main registers and inventories: (…)* - *Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;"*
(2)	**BASIS: GSR Part 6 para. 3.3. states that** *"The responsibilities of the regulatory body shall include: (…)* - *Establishing requirements for the collection and retention of records and reports relevant to decommissioning, and for preserving information about the activities that have been conducted at the site;"*
S10	**Suggestion: ENSI should consider updating decommissioning guidance to include provisions for the collection and retention of records and reports relevant to decommissioning, and for preserving information after termination of the license.**

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

Switzerland has implemented the following modal transport regulations for dangerous goods which include radioactive material (Class 7) and which are consistent with the IAEA Transport Regulations SSR-6:

- Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);
- Convention concerning International Carriage by Rail (COTIF) - Appendix C – Regulations concerning the International Carriage of Dangerous Goods by Rail (RID);
- European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN);
- Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO-TI);
- International Maritime Code for Dangerous Goods (IMDG-Code).

Based on these implementation procedures through the modal transport regulations for dangerous goods it can be concluded that the transport regulations for radioactive material in Switzerland comply with the IAEA Transport Regulations SSR-6.

The Swiss regulatory system is supported by several guides, such as:

- Technical Guide “Package Design Safety Reports for the Transport of Radioactive Material”, issued by the European Association of Competent Authorities (EACA);
- " Guidance for the Manufacture and Use of Packagings of Radioactive Material, Edition July 2015”, issued by ENSI, SUVA and FOPH.
- Guidance for transport licensing process including links to relevant regulations.

These documents are provided via ENSI website.

The above-mentioned guidance for the manufacture and use of packaging for radioactive material has been developed and issued by ENSI together with FOPH and SUVA. This guidance is considered useful because it explains and clarifies responsibilities of involved parties for manufacturing and using of packages in a quality assured manner in compliance with the requirements of the IAEA Transport Regulations within Switzerland. The scope of this document includes packages which are subject to testing and competent authority approval (packages of Type IP-2, IP-3, Type A and Type B) and consequently does not apply to excepted packages and packages of Type IP-1 for which in principle the same guidance is needed, especially because excepted packages are used very often in practice. ENSI is encouraged to initiate revision of this document together with FOPH and SUVA to include excepted packages and packages of Type IP-1 to cover all package types used in Switzerland.
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9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The legal framework for radiation protection in Switzerland is based on the RPA, RPO and a series of departmental ordinances applying to areas such as dosimetry, monitoring equipment, handling of radioactive materials, training and education.

A range of ENSI’s guidelines are relevant for the radiation protection in nuclear facilities. Some guidelines or FOPH directives have been drafted in collaboration among the different competent authorities (ENSI, FOPH, SUVA) and may be applicable on a broader range of installations and activities.

The guidelines encompass essential topics for occupational exposure, most importantly the guideline ENSI-G12 on “Radiation Protection in Nuclear Installations”, issued in September 2021, which is partially incorporating updated provisions from ENSI-G15 “Radiation Protection Objectives for Nuclear Installations”. Guidelines ENSI-B09 on “Determination and recording of doses to persons exposed to radiation” (ENSI-B04 and B09) and “Clearance of controlled and supervised areas and materials from mandatory licensing and supervision” (ENSI-B04) provide further and more detailed advisory material for the implementation of safety measures for occupationally exposed workers.

The revised RPO (2017) shows considerable alignment with IAEA standards for occupational exposure and shows a strong commitment to promoting a high level of protection and safety for exposed workers. There is however, a potential for improvement of regulations and guides owing to the following findings, of which many were already pointed out in the self-assessment:

1. The dose limits of GSR Part 3, Schedule III are not entirely implemented. It appears that the dose limits for young persons, 16-18 years of age do not fully comply with the GSR Part 3, schedule III with respect to the limit for equivalent dose to the lens of the eye of 20 mSv in a year and the limit for the equivalent dose to the extremities (hands and feet) or to the skin of 150 mSv in a year. The RPO should be checked against schedule III with respect to dose limits for this group.
2. There are no explicit requirements for the duration of data storage for the central dose register. Hence, it could not be verified that records of occupational exposure for each worker are maintained during and after the worker's working life, at least until the former worker attains the age of 75 years, and for not less than 30 years after cessation of the work.
3. There is no explicit requirement that the licensee has to inform a female worker about the risk of health effects for her breast-fed infant due to ingestion of radioactive substances. Art. 20 RPO appears too general.
4. There is no specific requirement in the regulations, stating that persons under the age of 18 years are allowed access to a controlled area only under supervision and only for the purpose of training for employment. Although access should always be justified, the requirement is important as it intrinsically implies that for this group of persons access is only justified if related to training/studies which is to the benefit to them.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The requirements of GSR Part 3 relating to the control of occupational exposure are not all addressed in the regulatory framework, such as those related to:* - *dose limits applying to young persons aged 16-18 applying to the lens of the eye and to extremities,* - *the retention of dose records,* - *special arrangements for female workers breastfeeding infants* - *persons under 18 years of age undergoing training.*	
(1)	**BASIS: GSR Part 3 para. 3.71. states that** *"The government or the regulatory body shall establish, and the regulatory body shall enforce compliance with, the dose limits specified in Schedule III for occupational exposure"*
(2)	**BASIS: GSR Part 3 para. 3.104. states that** *"… records of occupational exposure for each worker are maintained during and after the worker's working life, at least until the former worker attains the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure"*
(3)	**BASIS: GSR Part 3 para. 3.113. states that** *"Employers, in cooperation with registrants and licensees, shall provide female workers who are liable to enter controlled areas or supervised areas or who may undertake emergency duties with appropriate information on: (b) The importance for a female worker of notifying her employer as soon as possible if she suspects that she is pregnant or if she is breast-feeding; (c) The risk of health effects for a breastfed infant due to ingestion of radioactive substances"*
(4)	**BASIS: GSR Part 3 para. 3.116. states that** *"Employers, registrants and licensees shall ensure that persons under the age of 18 years are allowed access to a controlled area only under supervision and only for the purpose of training for employment in which they are or could be subject to occupational exposure or for the purpose of studies in which sources are used"*
R7	**Recommendation: The Government should revise the regulations concerning dose limits to young persons aged 16-18, retention of dose records, special arrangements for female workers breastfeeding infants and access to controlled areas for persons under 18 years of age undergoing training – in order to fully implement the safety requirements relevant for occupational exposure given in GSR Part 3.**

9.9. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The legal bases for the requirements concerning releases from nuclear facilities are outlined in the RPO and NEA. In addition, for each facility there is a specific regulation, for the release of radioactive substances, and the monitoring of radioactivity and direct radiation to the environment for a facility, required by ENSI in a formal order for the nuclear facilities. This facility-specific regulation includes requirements on release monitoring, describes the responsibilities between the relevant authorities and parties concerning the surveillance of the releases and the reporting of the licensee and the authorities. Examples of guidance are; the guideline ENSI-G13 on "Measuring Instrumentation for Ionising Radiation" (ENSI-G13) defining amongst other issues the requirements on the measuring devices used for the emission monitoring and the guideline ENSI-G14 for "Calculation of radiation exposure in the vicinity due to emissions of radioactive substances from nuclear installations" (ENSI-G14).

9.10. SUMMARY

The Swiss legal and regulatory framework provides a comprehensive and robust foundation for the regulatory oversight of the nuclear industry. ENSI implements and maintains a comprehensive set of guidelines that demonstrate a high level of quality in regulation for all nuclear facilities and activities.

The IRRS team observed that ENSI is fully committed to regularly updating its Regulatory Guides. ENSI actively participates in information sharing fora, collects and systematically explores national and international experience, and ensures that information regarding ENSI's regulatory requirements is widely available.

The IRRS team identified some areas for improvement such as the adoption of international standards, and modification and update of guidelines with due consideration of relevant international experience, retention of records and current IAEA requirements.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

ENSI has specific guidelines and Severe Accident Guidelines (SAMG) in relation to Emergency Exercises, Emergency Preparedness and Emergency Management in Nuclear Facilities. It has recently updated some of them.

For facilities in categories I and II, appropriate arrangements are in place to establish an on-site emergency plan to cover all the tasks that could be necessary when an on-site emergency is triggered.

According to RPO the Federal Office for Civil Protection (FOCP), together with the competent authorities and the cantons, is responsible for preparing the national emergency response plan for nuclear or radiological emergencies. ENSI informed the IRRS team of having completed its part. However, the national emergency plan for nuclear or radiological emergencies continues to be a draft and FOCP expects it to be issued in 2022.

Every nuclear facility has a large scope emergency exercise programme, which is developed in accordance with a graded approach, and implemented to ensure the availability and readiness for any emergency response organizations that warrant functions required to be performed in coordination with other organizations if required.

ENSI is informed of reportable events and inspects emergency exercises on a regular basis to warrant the operability of on-site emergency plans.

Four ENSI staff oversee the emergency preparedness and response (EPR) of nuclear facilities. Currently the Basic Inspection Programme includes topics related to EPR, e.g. the filtered containment venting systems, the operational readiness of the emergency ventilation system of the control room and emergency power supply systems.

As latest updates to the scope of inspections, ENSI decided to add the items:

- The process of updating and verification of emergency documentation,
- The operational readiness of the onsite and offsite emergency control centres,
- The process of warehouse management in the external emergency storage in Reitnau (common installation for all utilities where mobile equipment is stored).

Mobile equipment for emergency purposes which are located at the NPPs and at the Reitnau emergency storage are included in ENSI's 10-year inspection programme.

Inspection and evaluation of emergency exercises at NPPs are carried out calling upon the expertise of several disciplines within ENSI. The evaluation of firefighting brigades at the site lies within the responsibility of the canton where NPP is located. As responsibilities for overall EPR in Switzerland are shared at the local, the regional and the national level, ENSI staff, with its expertise in NPP related matters, contributes to the improvement of EPR at local, regional and national levels.

ENSI staff for EPR is also involved in international activities on EPR, such as in the IAEA's Emergency Preparedness and Response Standard Committee, bilateral working groups and in the Working Group on Emergencies of the Heads of the European Radiation Protection Competent Authorities (WGE-HERCA).

ENSI is a key player in the national EPR-network. For the purpose of coordination and setting the national objectives and strategy to cope with a nuclear or radiological emergency, a nuclear or radiological emergency plan (NREP) is requested according to RPO Art. 135. A first draft is available, signed three months ago.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Currently there is only a draft national nuclear and radiological emergency plan. There is no established road map for finalizing and implementing the national nuclear and radiological emergency plan.*	
(1)	**BASIS: GSR Part 7 para 4.5. states that** *"The government shall make adequate preparations to anticipate, prepare for, respond to and recover from a nuclear or radiological emergency at the operating organization, local, regional and national levels, and also, as appropriate, at the international level. These preparations shall include adopting legislation and establishing regulations for effectively governing the preparedness and response for a nuclear or radiological emergency at all*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	levels"
S11	**Suggestion: The Government should consider expediting the finalization and implementation of the national nuclear and radiological emergency plan.**

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

The legal basis and guidelines ensure that that the operating organization is given sufficient authority to promptly take necessary protective actions on the site in response to a nuclear or radiological emergency that could result in off-site consequences. ENSI has updated or is planning to update specific EPR-related guidelines.

Licensees have an obligation to notify authorities immediately in case of any event which triggers the on-site emergency plan. The initial notification is made orally via phone. Following NEO Annex 6, licensees are required to send authorities a written confirmation of the initial notification. However, no time criterion has been set for this confirmation.

It is required that licensees review appropriately the on-site emergency plan, when necessary and prior to any change in the facility or activity that affect the existing hazard assessment. In this sense on the basis of the hazard identified and the potential consequences of a nuclear or radiological emergency, protection strategies are developed justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency to achieve the goals of emergency plan response.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Licensees have an obligation to notify authorities immediately in case of any event which triggers the on-site emergency plan. The initial notification is made orally via phone. Licensees are required to send authorities a written confirmation of the initial notification. However, there are no set time criteria for this confirmation.*	
(1)	**BASIS: GSR Part 7 para 5.11. states that** *"…The notification point(s) shall be able to initiate immediate communication by suitable, reliable and diverse means with the response organizations that are providing support."*
(2)	**BASIS: GSR Part 7 para 5.17. states that** *"For facilities and activities in categories I, II and III, and for category IV, arrangements shall be made: (1) to promptly recognize and classify a nuclear or radiological emergency; (2) upon classification, to promptly declare the emergency class and to initiate a coordinated and pre-planned on-site response; (3) to notify the appropriate notification point (see para. 5.11) and to provide sufficient information for an effective off-site response; and (4) upon notification, to initiate a coordinated and pre-planned off-site response, as appropriate, in accordance with the protection strategy. These arrangements shall include suitable, reliable and diverse means of warning persons on the site, of notifying the notification point (see paras 5.41–5.43, 6.22 and 6.34) and of communication between response organizations."*
(3)	**BASIS: GS-G-2.1 para 3.5. states that** *"The operator should be responsible, as appropriate, for: …Establishing ongoing communication with off-site officials; …"*
S12	**Suggestion: ENSI should consider modifying ongoing communication practices by establishing a criterion for the timely written confirmation of the initial notification of a nuclear or radiological emergency by the licensee.**

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

Licensees determine the emergency class based on Emergency Action Levels (EAL) and in accordance with the IAEA recommendations. The classification scheme is laid out in the revised Nuclear Emergency Ordinance. Adhering to a graded approach, EAL were introduced in priority for nuclear facilities with the potential of off-site radiological consequences. The introduction of EAL for the zero-power research reactor in Lausanne is planned, despite of negligible radiological consequences.

In case of an emergency, a teleconference is organised by the National Emergency Operation Centre (NEOC) between ENSI, the NEOC, the home canton of the nuclear facility and the licensee. The aim of the teleconference is to share information on the accident or incident, the declared emergency class and decide upon off-site measures.

Duties and responsibilities of the licensee in an emergency are notably laid out in the Ordinance on the Protection in case of Emergency (OPCE). In the event of an emergency, the licensees analyse the incident in respect of its danger to the population, they initiate suitable measures to control the incident and to limit its impact on the workers and the population. They timely inform ENSI and NEOC. In addition, they inform cantonal bodies. ENSI makes forecasts about the development of the accident within the plant, about the possible dispersion of the radioactive material in the environment, and about the consequences of such dispersion.

The licensee determines the source term and communicates it to ENSI.

In that respect, information about evolving on-site conditions, the possible upgrading or downgrading of the prevailing emergency class, is also provided by the license holder within the telephone conference calls. The information provided by the license holder emergency organization is paramount for off-site authorities to assess potential hazards to the environment and the population originating from an accidental nuclear facility.

Hence, though no conditions, criteria or objectives are explicitly set out for the termination of an emergency on the site, the license holder will implicitly uphold its emergency organisation as long as the risk for off-site consequences requiring urgent protective actions is considered to persist.

In this regard, ENSI can also, order measures aimed at preserving nuclear safety and security towards the license holder. The documentation of data and information important for event analysis is ensured requiring that the licence holder must at all times traceably document the operation of the installation on the basis of records and securely archive it until completion of the decommissioning or until closure of the installation or expiry of the specified monitoring period. Accident instrumentation used in emergency management is required to allow tracing and documentation of the accident progression for further analysis.

The emergency organisation on-site continuously analyses the progression of an event taking immediate measures to avoid an extension of the event and to take at earliest those measures necessary for the management of it

Independently of the event that triggers the on-site emergency plan, an event report with follow-up reports has to be submitted to ENSI, hence setting the framework for the identification and initiation of actions, including to improve emergency preparedness arrangements where appropriate. Within the context of the periodic safety review, the license holder is further required to analyse emergency preparedness in particular with regard to past events and assess overall on-site emergency preparedness arrangements for maintaining and optimizing emergency preparedness.

Adequate manning by qualified personnel of the onsite emergency organisation is required for long term operation capability. Requirements for prompt staffing are equally set forth.

The operating license is granted by DETEC if the appropriate measures for dealing with emergencies have been prepared and further specifies that the emergency measures to be taken by the license holder during operation of the installation constitutes an integral part of the operating license.

NEA Art. 65 specifies that modifications, which do not significantly deviate from the granted license, but however could impact on nuclear safety or security, require a permit from ENSI.

Emergency regulations is subject to a permit if their contents are changed. Changes are required to be justified in the application for such a permit. ENSI guidelines requires the license holder to analyse national and international operational experience and outline the insights and derived measures for its own facility. This includes insights affecting onsite emergency preparedness arrangements. ENSI is responsible for enforcing requirements set out in in the legislation and the subsequent guidelines issued.

ENSI may contribute to the formulation process of long-term protective actions. It may contribute by setting up the technical basis for long term actions, namely by:

- Providing up-to-date maps of potentially contaminated areas, to be confirmed through sampling and measurements;
- Providing resources to the measurement and sampling organization;
- Providing radiation protection expertise to the BSTB.

The ENSI´s emergency organization consists of:

- A director of operations;
- A chief of staff;

- A stand-by engineer on duty;
- A journal keeper;
- ENSI-Task Force “Reactor Safety”;
- ENSI-Task Force “Radiation Protection”;
- ENSI-Task Force “Information”;
- ENSI-Task Force “Infrastructure”;
- ENSI-Task Force “Special functions”.

Every employee of ENSI is part of the emergency organization and carries out the tasks and functions assigned. The assignment of ENSI staff within the emergency organization takes into account as much as possible the individual competence and experience.

The performance of the emergency organization staff is tested at least once a year during Plant Emergency Exercises organised at the nuclear installation’s sites and in all General Emergency Exercises taking place biennially.

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

According to Ordinance of Protection in the Case of an Emergency (OPCE) ENSI maintains an on-call internal emergency organization and a stand-by emergency service (stand-by engineer on duty) and operates a network of automatic dose rate monitors in the vicinity of NPPs. In a nuclear or radiological emergency, ENSI is responsible for:

1. Informing the NEOC immediately about events in Swiss nuclear facilities,
2. Assessing the measures taken by the operators of the nuclear facilities and monitoring their implementation,
3. Making predictions about the development of the accident within the plant, about the possible dispersion of the radioactivity in the environment, and about the consequences of such dispersion,
4. Advising the Swiss Federal Office for Civil Protection (FOCP) and the Federal Civil Protection Crisis Management Board (BSTB) in ordering protective measures for the population,
5. Rating the event according to the International Nuclear Events Scale (INES) of the IAEA.

In the event of a crisis, the emergency organisation makes use of the crisis communication concept, prepared working instructions, checklists for various types of crisis, telephone lists, prepared language rules (German, French, Italian and English) and practised procedures. An inspected Plant Emergency Exercise is held annually at all nuclear facilities. On the one hand, the Communication Section takes part in these exercises and, on the other, evaluates the corresponding communications work of the nuclear power plants. The ENSI emergency organisation is integrated into the national emergency organisation. Every two years, the Federal Office for Civil Protection conducts a General Emergency exercise in which a nuclear power plant, the site canton, the cantons, villages and the National Emergency Operations Centre and ENSI participate.

ENSI has an emergency Response Centre at Brugg. The alternate emergency centre in Schlieren is operational since the beginning of August 2021 and can be activated anytime since then. The activation process yet needs to be reflected in the emergency management documentation. This is being taken care within the ongoing revision of the emergency preparedness process.

Within the national measurement and sampling organisation, ENSI provides mobile measurement capability. ENSI may issue orders to the licensee to preserve nuclear safety and security or in case of an imminent danger order measures deviating from the granted license. To comply with its duties, ENSI uses among others its JRODOS atmospheric dispersion calculation system, plant data (ANPA) forwarded by the facility (only NPPs) and its network of dose rate monitors (MADUK) in the vicinity of the nuclear facilities.

Being a member of the BSTB, ENSI has the duties and responsibilities set out of the corresponding VBSTB ordinance: to coordinate with other actors involved in the emergency management and to contribute to prepare the document basis for decisions to be taken by the Swiss Federal Council.

The NEOC notifies and informs the IAEA and neighbouring states in accordance with the relevant agreements in this area. ENSI supports the NEOC in the notification process with recommendations and technical data on the

situation and developments at the NPP. The information outflow in an emergency is addressed in the ENSI's Management System, as well as in an agreement between the Federal Department of Defence, Civil Protection and Sport (DDPS), DETEC, the Federal Chancellery, the cantons of Solothurn, Aargau, Bern and the licensees of nuclear facilities (NPP's incl. ZWILAG and PSI).

In an emergency, ENSI informs NEOC on technical matters concerning the plant, the assessment of the conditions at the site, the probable evolution of the conditions at the site and radiological forecasts for the event. The preparation of long-term protective actions lies within the responsibility of the BSTB and the federal offices represented therein. The main offices involved will be the FOPH, the Swiss Federal Office for Agriculture (FOAG) and the FOCP along with the NEOC and the sampling and measurement organization.

10.5. SUMMARY

The authority and responsibilities of ENSI are clearly defined in Swiss legal framework with regard to regulating the on-site emergency arrangements of the operating organizations and verifying the compliance of the on-site emergency arrangements of operating organizations with the regulatory requirements. Coordination amongst organizations with relevant authority and responsibilities in regulating EPR of operating organizations is ensured.

ENSI has adequately allocated resources and an organizational structure to fulfil its responsibilities in regulating the EPR of the licensees. ENSI also applies graded approach in regulating EPR. ENSI issues guidelines addressing the requirements and guidance for emergency arrangements to be put in place by the licensees of nuclear facilities and activities that could necessitate emergency response actions. Authority is given and responsibilities are assigned to the licensees to promptly decide on and take necessary mitigatory and protective actions on-site in a nuclear or radiological emergency. To ensure timely and reliable notifications from the licensees in case of an emergency, the IRRS team suggests ENSI to establish a time criterion for the written confirmation of the initial notification. Mechanisms are in place to ensure that licensees review and, as appropriate, revise their emergency arrangements. ENSI has established various means and carries out inspections to verify the adequacy of onsite EPR of licensees prior to commencement of operation and throughout the lifetime of the facility or activity. ENSI is given the authority to enforce and follow-up corrective actions in relation to on-site EPR of licensees. The integration of on-site emergency arrangements of licensees with those of relevant off-site response organizations and with other plans is ensured. Switzerland has clearly assigned the roles in response to any nuclear or radiological emergency. For further enhancement of national emergency arrangements, the IRRS team suggests the Government to expedite the finalisation and implementation of the national emergency plan for nuclear or radiological emergencies.

ENSI has established internal preparedness arrangements to fulfil its role in emergency response. In its self-assessment ENSI has identified areas for improvement related to updating of ENSI guideline on "Application documents for modifications to nuclear installations requiring a permit" and by setting up a comprehensive training programme in EPR for ENSI's emergency organization. The IRRS team supports ENSI's self-assessment results.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

Switzerland is a signatory to the Treaty on Non-Proliferation of Nuclear Weapons (NPT) and Convention on the Physical Protection of Nuclear Material (CPPNM) and its Amended Convention on Physical Protection of Nuclear Material (CPPNM/A).

In 2003, the basis for a regulation covering both safety and nuclear security was introduced in NEA. In 2009, ENSI was separated from SFOE by the enforcement of the Federal Act on the Swiss Federal Nuclear Safety Inspectorate and the supervision of safety and nuclear security was assigned to ENSI. The responsibility for nuclear safeguards still remained within SFOE (role and responsibilities defined in Art. 72 of NEA and Art. 6 of NEO).

NEA is the principal act establishing overall duties and responsibilities with regard to security of nuclear material and facilities and NEO contains detailed provisions. Requirements for safety and nuclear security are specified in article 4 and 5 of NEA and both safety and nuclear security requirements are required to be fulfilled. In addition, a number of other acts and ordinances cover specific aspects of nuclear security.

SFOE is the federal authority for the implementation of safeguards based on Art. 6 of NEO and Art. 4 of the Safeguards Ordinance, its duties and powers are described in Art. 72 of NEA and in the Safeguards Ordinance.

The responsibilities for the integration of response force capabilities in case of nuclear security-related incidents are assigned to the license holder and the details are described in Art. 19 of the Swiss Ordinance on Security Guards of Nuclear Installations.

The Swiss legislation defines the legal basis and role of individual authorities for safety, nuclear security and safeguards and the interface among the concerned authorities are established.

11.2. REGULATORY OVERSIGHT ACTIVITIES

Requirements for safety and nuclear security measures are specified in Art. 5 of NEA and both safety and nuclear security requirements must be met. This is reflected in the processes of ENSI's Management System as well as in ENSI guidelines. Some ENSI guidelines consider both safety and nuclear security related topics and some guidelines are specific to nuclear security because they contain sensitive matters. ENSI intends to consider safety and nuclear security in one guideline whenever possible in order to effectively address the safety-security interface. During the IRRS Self-Assessment, ENSI identified a need to add provisions for systematic security assessments required in Art. 33 NEO to an ENSI guideline as an area for improvement, which is reflected in ENSI's 2021 IRRS Action Plan.

After its establishment, ENSI is the only regulatory authority for nuclear safety and security at nuclear facilities and coordination between the two aspects can be conducted internally. If conflicts between safety and nuclear security requirements arise, a solution that adequately considers both safety and nuclear security needs is pursued through a case-by-case analysis following the procedure for coordination laid down in ENSI's Management System (HPB0100 "Transaction & Project Management" Chapter 2).

Both safety and nuclear security requirements are addressed in the Swiss legislation and reflected in ENSI's Management System, but they are described individually without referring to the interface between them. The consideration of safety and nuclear security requirements are properly dealt with by ENSI during its review and assessment process and once a potential conflict between safety and nuclear security is identified. ENSI has a process to address the issue. However, without explicit recognition of the interface between safety and nuclear security, potential interference between safety and nuclear security might be overlooked. ENSI acknowledge the necessity to address the interface between safety and nuclear security in an integrated manner and now consider to refer it explicitly in its management documents.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: *Both safety and nuclear security requirements are addressed in the Swiss legislation and reflected in ENSI's Management System. The consideration of safety and nuclear security requirements are properly dealt with by ENSI during its review and assessment process and once any conflict between safety and nuclear security is identified, ENSI has a process to address the issue. The interface between safety and nuclear security should be well documented in the ENSI's management system to identify potential conflict and ensure that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 2.40. states that** *"Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security."*
S13	**Suggestion: ENSI should consider ensuring that the interface between safety and security is well documented in its management system to identify potential conflict and ensure that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.**

11.3. INTERFACE AMONG AUTHORITIES

A number of acts and ordinances comprise various provisions in order to ensure coordination and cooperation among the authorities (e.g. obligation to provide administrative assistance or provisions to settle conflicts regarding jurisdiction in administrative proceedings). Such coordination and cooperation take place based on the Government and Administrative Organization Ordinance, which requires cooperation between the administrative units and participation of concerned administrative units.

Arrangements for the interfaces between safety and safeguards are essentially established between the nuclear security section at ENSI and the safeguards section at SFOE at regular bilateral meetings. The so-called Group of Nuclear Partners (GNP) also conduct meetings at regular intervals with all government authorities involved in nuclear security. The GNP comprise experts from various governmental organizations on a federal level, with the objective of comprehensive sharing of relevant information about their activities and topical knowledge, in order for all involved institutions to maintain updated knowledge and coordination.

On the other hand, the liaison between ENSI and law enforcement agencies is specified in chapter 9 of NEA, but it only covers criminal provisions. Article 72 of NEA stipulates relationships to the police and to the customs authorities, but it is also limited to their supports for investigation and enforcement. Regarding the interface between safety and nuclear security, there are no particular arrangements to facilitate the communication and coordination between ENSI and police forces. In order to facilitate closer communication and coordination, ENSI's management system could preferably address liaison with law enforcement agencies more explicitly.

11.4. SUMMARY

The NEA establishes the overall duties and responsibilities with regard to nuclear security whereas a number of other acts and ordinances cover the more specific aspects. Both, safety and nuclear security requirements are addressed in the Swiss legislation and reflected in ENSI's Management System. Supervision of nuclear safety and security are united in ENSI and the interface to safeguards under the responsibility of SFOE was established when ENSIG came into force.

ENSI should consider ensuring that the interface between safety and nuclear security is well documented in its management system to identify potential conflict, warranting that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.

The Swiss federal legislation clearly defines the duties and responsibilities of the authorities having responsibilities for safety and nuclear security and it also contains various provisions in order to ensure coordination and cooperation among the authorities. For further facilitation of close communication and coordination regarding the interface between safety and nuclear security, ENSI's management system could preferably address liaison with law enforcement agencies.

12. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS

12.1 GOVERNMENTAL AND LEGAL FRAMEWORK FOR SAFETY

The Swiss Federal Council declared in Switzerland an "extraordinary situation" and introduced emergency measures on 16 March 2020, based on the Swiss Epidemics Act. The Covid-19 Act (Federal Act on the Statutory Principles for Federal Council Ordinances on Combating the Covid-19 Epidemic) was promulgated by the Swiss Parliament on 25 September 2020. The Covid-19 Act provides provisions on measures relating to the justice system and procedural law, allowing the Swiss Federal Council to issue provisions to suspend, extend or restore statutory or official limitation periods and deadlines on civil and administrative matters.

The Covid-19 Act provided also the legal basis allowing the Swiss Federal Council to maintain the emergency measures that were still necessary to manage the Covid-19 epidemic. In addition, the Federal Council promulgated a number of Ordinances on combating the Covid-19 pandemic in:

- Measures to Combat the Coronavirus (COVID-19);
- Measures during the Special Situation to combat the COVID-19 Epidemic;
- The Proximity Tracing System for the Sars-CoV-2 coronavirus;
- Measures for public events of inter-cantonal significance in connection with the covid 19 epidemic:
- Measures to Combat the Coronavirus (COVID-19) in International Passenger Transport.

However, except the health-care related measures, these Ordinances do not include any special measures for critical infrastructures, such as those related to nuclear and radiation safety.

12.2 REGULATORY FRAMEWORK

According to the Risk Management procedure (HPB0070), a working group composed of members of the ENSI Board, the Executive board and ENSI's risk manager (SRM) was set up to assess the risks periodically and identified measures to ensure that critical business functions were maintained. Then, a pandemic plan was developed and implemented to face the pandemic situation. Inter alia, this plan provided for the minimum level of personnel to be present at ENSI premises.

ENSI took several measures to protect its employees' health depending in accordance with the national directives (e.g., wearing a mask, social distancing, hygiene measures, keeping a contact log, medical controls at the entrance). Information from the Director General to the staff was given through video conferencing.

ENSI changed neither its general organisational structure nor the allocation of resources within its organization during the pandemic situation. The number of staff present at ENSI's premises in Brugg was reduced depending on the different phases of the pandemic situation. At the peak of the pandemic, only 15% of ENSI's staff were physically present at one time. To ensure the business continuity, one person per section was required to work at the office, who acted as the contact person for the staff working from home. There was no reduction of staff resulting from the pandemic situation.

Working from home was possible and was even encouraged, depending on the pandemic situation. Actually, the IT-infrastructure was strengthened to facilitate the teleworking before the pandemic, in late 2019 when the possibility of working at home was officially introduced. So, ENSI had already some experience in relation to the teleworking. Before the pandemic, around 20% of ENSI staff were already working from home on an irregular basis. Some improvements were further made shortly after the lockdown started, including the installation of several electronic communication tools, facilitating further the work from home. Through a secure internet connection, the ENSI's employees have a secure and fast access to all applications and files available on ENSI's servers. In this regard, more than 90% of ENSI's records and files are available as electronic documents, and all new incoming files and documents are digitalized systematically. The electronic signature is not yet available at ENSI and there were basically no changes into the decision-making processes.

12.3 REGULATORY FUNCTIONS

As described below, there were no significant changes in performing regulatory functions resulting from the pandemic. The stability and consistency of the regulatory control were not affected. This is mainly due to the ENSI regulatory processes which are formal processes with several different instruments that are used to ensure that they are implemented consistently and with management control.

Regulatory decisions that need formal signed documents were issued and the regulatory authorization activities were not affected. However, ENSI did not have at the time of the mission the possibility of electronical signature.

Protection measures were also taken in the authorized parties which in the NPPs were mostly supervised by SUVA and FOPH. Some measures, such as the minimum staffing levels and the specific regulations were formally approved by ENSI. The nuclear reactor must be shut down if the number of staff fall below a required threshold. There had been no critical shortage of personnel in the facilities given the border control measures always allowed persons to enter Switzerland for work-related reasons. However, some NPPs shortened outages due to limited availability of external personnel. In all NPPs, the scope of tests and maintenance work was reduced, and non-essential plant modifications were postponed. Nevertheless, all critical works and tests were carried out in all NPP at all times. ENSI reviews the NPP outage plans and monitors the work activities.

There were no delays in regulatory review and assessment of documents and applications. This is why neither postponement of the implementation of the routine licensing regime nor delay in the fulfilment of conditions of the authorisations have been reported. Formal regulatory decisions, e.g. permits, were granted during the pandemic.

The ENSI's inspection programme was not changed substantially. Nevertheless, because of the available workforce was more limited for NPP outage, the licensees requested to postpone several in service inspections and maintenance activities. These requests were reviewed and approved by ENSI; these postponed activities were implemented one year later. The access to the nuclear facilities was not limited. ENSI performed on-site regulatory inspections throughout the pandemic, but the number of the staff participating to the inspections was reduced to a minimum. Additionally, during the lockdown, there was a postponement of non-activity-bound inspections and no team inspections. To compensate for this, ENSI conducted a limited number of remote inspections.

Special additional rules and health measures were put in place for inspectors, who also followed the Covid protocols in place at each site. The relatively close proximity of nuclear facilities to the ENSI office in Brugg provided the ability to safely travel for reactive inspections as needed through use of personal vehicles. The environmental monitoring and monitoring of discharges, including on-site measurements and collecting of samples was uninterrupted.

In the area of transport, problems appeared with the inspection of manufacturing of packaging which takes place in the USA. Experts from Switzerland had to postpone their regulatory visits but introduced instead remote-controlled activities from Switzerland by using video transmissions and video conferences together with USA experts at the manufacturing site. There was certainly a delay but overall the experience was very positive with the use of such remote regulatory procedures. ENSI may continue to use them in the future, where appropriate.

ENSI's communication and consultation activities were not significantly affected: most regular and ad-hoc meetings were performed virtually (e.g., with authorised parties, advisory bodies and support organizations). Exchange of documents was not affected but mostly done in an electronic way. ENSI noted that during the unusual circumstances, the number of requests from the public was lower than usual but the number of requests from governmental offices was higher.

Internal trainings where physical presence was mandatory, were suspended. All other training activities for maintaining competencies were conducted on-line. ENSI also performed accreditation of personnel partly via video conferencing.

During the pandemic, ENSI kept in touch with its essential technical services providers and confirmed that they continued performing all their essential activities.

ENSI performed all its essential regulatory functions during the pandemic. No specific issues of safety significance were raised. ENSI identified a list of challenges and future work based on the experience so far. Some of these are:

- Prepare transition to "normal situation";
- Develop further protective measures for non-vaccinated staff;
- Update pandemic plan;
- Check further internal processes for revision;
- Study the establishment of remote inspections (legal, technical);
- Update readiness for EPR measures at ENSI and at national level;

- Measures for improving teamwork and enhancing resilience and mental health of its staff.

12.4 EMERGENCY PREPAREDNESS AND RESPONSE

Overall, ENSI did not diminish its level of readiness to face any emergencies. However, a couple of measures were taken to avoid the contagion spreading, such as the use of the emergency bunker limited only to real emergency situations. Only one emergency exercise was cancelled. On the other hand, there was no delay for the review of events in nuclear facilities.

At the emergency preparedness and response of the licensees, the emergency exercises were carried out according to ENSI-B11 "Emergency Exercises" guideline but in adapting the scope and the number of staff involved to a minimum acceptable. The licensees' documentation and measures to guarantee effective emergency preparedness and response under pandemic circumstances was submitted to and reviewed by ENSI.

12.5 OVERVIEW AND MAIN CONCLUSIONS OF THE POLICY DISCUSSION

Regulatory bodies and competent authorities initiated a number of measures to maintain the delivery of their statutory regulatory functions and to contribute to the safe operation of facilities and conduct of activities, during the COVID-19 pandemic. In order to contribute to the experience sharing and exchange of lessons learned between the IRRS team and ENSI, a policy discussion was held on the Regulatory Implications of Pandemic Situations. The discussions focussed on the conduct of remote regulatory inspections and participation to the emergency preparedness and response remotely.

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

- Several countries reviewed their legal framework to ensure there was an appropriate basis to conduct remote inspections. In those countries, no restrictions were identified to conduct such inspections;
- The regulatory bodies had to adjust their inspection programme, and have conducted a number of inspections remotely or according to a hybrid format, i.e., inspections conducted in presence of inspectors, usually resident or site inspectors, with a remote participation of other inspectors or regulatory experts;
- The preservation of the confidentiality of information when inspecting remotely is a challenge which deserves special attention. When inspectors cannot get remote access of relevant data and documents, physical inspections have to be conducted;
- A full response to an emergency situation in a remote format is challenging. However, some regulatory bodies consider that a hybrid approach for emergency responses is feasible;
- The importance to prepare a business continuity contingency plan addressing different types of threats, was highlighted as well as the need to ensure the IT environment provides for effective remote work.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
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GROUP PHOTO

APPENDIX II – MISSION PROGRAMME

Mission Schedule | 1st Week

Time	SAT	SUN	MON	TUE	WED	THU	FRI	SAT	SUN
9:00-12:00	Arrival of Team Members		Entrance Meeting	Interviews	Interviews; TL, M1 expert and TC meet DETEC in Bern	Interviews and Visits; DTC writes introductory parts	TM write Report TL and DTL review introductory part **Draft text to TL**	• Discussing and improving Draft Report • Cross-Reading • TL, DTL, TC and DTC read everything	Free day, Social Tour
12:00-13:00			Lunch with Host	Standing lunch					
13:00-14:00		IRRS Initial Team Meeting		Interviews	Interviews	Interviews + Visits; DTC writes introductory parts	Policy Discussions	Finalisation of the Draft Report	
14:00-15:00			Interviews (individual or in groups)						
15:00-16:00							Secretariat edits the report **Preliminary Draft Report Ready**; Cross-reading by TM		
16:00-17:00					**Written preliminary findings delivered**				Reading, cross-reading of the draft report if needed
17:00-18:00			Daily Team Meeting	Daily Team Meeting	Daily Team Meeting: **Discussion of findings**	Daily Team Meeting	Daily Team Meeting		
18:00-20:00		Team Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	
20:00-24:00			Writing of the report	Writing of the report	Daily Team Meeting: Discussion of findings	Writing of the report	TM Read Draft	Secretariat edits the report	

Mission Schedule | 2nd Week

	MON	TUE	WED	THU	FRI
					Submission of the Preliminary Report
9:00-10:00	Discussion of Recommendations, Suggestions and Good Practises with counterparts by module	Cross-Reading of the Report TL, DTL, TC and DTC read everything Finalisation	Common read through and finalisation of the Report by the Team	Host reads Draft Report	Exit Meeting Press Conference Publication of Press Release
10:00-12:00			Submission of the Draft to the Host	Team discusses the Mission and provides IAEA with feedback	Lunch
12:00-13:00	Standing lunch	Standing lunch	Lunch	Standing Lunch	
13:00-15:00	Individual discussions of Recommendations, Suggestions and Good Practises with counterparts	Discussion of the Report by the Team; TC, DTC prepare Executive Summary and exit presentation	Host reads Draft Report; TL finalises Executive Summary and Exit Presentation; TC Drafts the Press Release	Written comments provided by the Host Team meeting to discuss and resolve Host comments	Departure of the IRRS Team
15:00-17:00				Plenary (Team + Host) to discuss Host comments and finalize the report	
17:00-18:00	Daily Team Meeting		Discussion of Executive Summary and delivery to the Host	Briefing of the Senior IAEA Manager. Finalisation of the press release and of the Preliminary Report	
18:00-20:00	Dinner	Dinner	Dinner	Farewell Dinner	
20:00-21:00	Secretariat updates Report	Secretariat finalises Report	Free		
21:00-24:00				Free	

APPENDIX III – SITE VISITS

1. Paul Scherrer Institute (PSI), Hotlab and dosimetry service
2. Beznau NPP
3. Mühleberg NPP
4. Gösgen NPP
5. Swiss Federal Institute of Technology Lausanne (EPFL), CROCUS research reactor

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff
1.	**LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES**		
	Mr Igor Sirc	Mr. Marc Kenzelmann, Director General	Mr. Andreas Schefer, Chief of Staff
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Mr Tomoho Yamada	Ms. Annatina Müller-Germanà, Head of International Affairs	Mr. Hugo Nilsson, Specialist International Affairs Ms. Annette Ramezanian, Head of Site Inspections
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Mr Thomas Wildermann	Mr. Andreas Schefer, Chief of Staff	Mr. Peter Flury, Deputy Chief of Staff Ms. Stefanie Oehler, Head of Communication Ms. Tamara Garny, Director Division of Resources Mr. Reiner Mailänder, Deputy Head of International Affairs and Research Coordinator
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Mr Naveed Maqbul	Mr. Jean-Claude Veyre, Head of Quality Management	Ms. Tamara Garny, Director Division of Resources Ms. Cornelia Ryser, Specialist Human and Organisational Factors
5.	**AUTHORIZATION**		
	Ms Pepa Stoyanova Todorova Mr Sergii Iegan Ms Anki Hägg Mr Mario Dionisi Mr Frank Nitsche Mr Kresten Breddam	Mr. Klaus Theiss, Deputy Director Division of NPPs	Mr. Patrick Tschudin, Specialist Law

	IRRS EXPERTS	Lead Counterpart	Support Staff
6.	**REVIEW AND ASSESSMENT**		
	Ms Jianxiu Cheng Mr Sergii Iegan Ms Anki Hägg Mr Mario Dionisi Mr Frank Nitsche Mr Kresten Breddam	Mr. Ralph Schulz, Director Division of Safety Analyses	Mr. Gerhard Schoen, Head of PSA & Accident Management Section
7.	**INSPECTION**		
	Mr Geoffrey Miller Ms Helene Vacelet Mr Sergii Iegan Ms Anki Hägg Mr Mario Dionisi Mr Frank Nitsche Mr Kresten Breddam	Mr. Georg Schwarz, Deputy Director General	Mr. Giuseppe Testa, Head of Occupational Radiation Protection Section and Head of Inspection Process
8.	**ENFORCEMENT**		
	Ms Helene Vacelet Mr Geoffrey Miller	Mr. Andreas Schefer, Chief of Staff	Mr. Christoph Perrass, Law Specialist
9.	**REGULATIONS AND GUIDES**		
	Ms Anupama Bulkan Mr Sergii Iegan Ms Anki Hägg Mr Mario Dionisi Mr Frank Nitsche Mr Kresten Breddam	Mr. Peter Flury, Deputy Chief of Staff	
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	Mr Jose Martin Calvarro	Mr. Ronald Rusch, Head of EPR Section	Ms. Rosa Sardella, Director Division of Radiation Protection

	IRRS EXPERTS	Lead Counterpart	Support Staff
11.	**ADDITIONAL AREAS**		
	Mr Tomoho Yamada	Mr. Bernhard Stauffer, Head of Nuclear and Cyber Security Section	Mr. Hans Mattli, Specialist Nuclear Security Ms. Rosa Sardella, Director Division of Radiation Protection

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

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	**R1**	The Government should evaluate the needs for building and maintaining competence of the parties that have responsibilities in relation to safety of facilities and activities in the near, mid-term and long-term future. It should then establish the appropriate strategy to fulfil those needs.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**S1**	ENSI should consider revising the set of criteria used in the contracting procedure to ensure that only independent experts devoid of conflicts of interests are contracted.
	R2	The Government should include an obligation in the regulatory framework for the authorized party to inform the public about safety relevant occurrences in their facilities.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**S2**	ENSI should consider establishing a systematic competence development framework to assess possible gaps to take further actions and to achieve and sustain the desired level of competence of the staff.
	GP1	ENSI's activities with regards to organizational safety and its oversight culture were found remarkable for effective development and continuous improvement of a culture of safety in the organization.
5. AUTHORIZATION	**R3**	The Government should establish provisions to ensure that all nuclear facilities will be subject to periodic safety reviews at predefined intervals, in accordance with a graded approach.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
6. REVIEW AND ASSESSMENT	**S3**	ENSI should consider, in the training of staff, to better address the graded approach in review and assessment of non-NPP nuclear facilities, in order to improve the application of relevant ENSI guidance material.
	S4	ENSI should consider revising its internal guidance for review and assessments of package designs to include guidance for the assessment of mechanical, thermal and radiation safety together with the existing guidance on criticality safety in a consistent manner.
	S5	ENSI should consider expediting the revision of the guidelines concerning the methodology for calculation of the radiation dose to the representative person used for the assessment of the dose to the public for planned exposure situations.
7. INSPECTION	**S6**	ENSI should consider developing a set of documented criteria based on a graded approach for use in decision-making for the appropriate level of reactive inspection response for special circumstances.
	GP2	The safety culture focus groups are an effective tool for proactively engaging the senior management of NPP operators to promote self-awareness of their impact as leaders on the safety culture of their organizations.
	S7	ENSI should consider reviewing and revising its inspection instructions for transport in compliance with applicable inspection activities, such as described in TS-G-1.5.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
8. ENFORCEMENT	**R4**	The Government should ensure that the legal framework - given the importance of safety culture – also allows prosecution of a licensee instead of an individual.
	R5	ENSI should update its enforcement procedures in relation to immediate corrective actions inspectors are authorized to take if there is an imminent likelihood of safety significant events.
9. REGULATIONS AND GUIDES	**S8**	ENSI should consider updating the process for revising guidelines to include relevant international operating experience as a criterion for recommending modifications to guidelines during the annual review.
	R6	In cases where ENSI adopts international standards in place of creating a guideline, ENSI should clarify the process for the adoption of the standard, and notifying and facilitating consultation with interested parties.
	S9	ENSI should consider completing the revision of guideline ENSI-G07 to be aligned with GSR Part 2 Safety Requirements and to strengthen the criteria for the systematic management of CFSI.
	S10	ENSI should consider updating decommissioning guidance to include provisions for the collection and retention of records and reports relevant to decommissioning, and for preserving information after termination of the license.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R7	The Government should revise the regulations concerning dose limits to young persons aged 16-18, retention of dose records, special arrangements for female workers breastfeeding infants and access to controlled areas for persons under 18 years of age undergoing training – in order to fully implement the safety requirements relevant for occupational exposure given in GSR Part 3.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	**S11**	The Government should consider expediting the finalization and implementation of the national nuclear and radiological emergency plan.
	S12	ENSI should consider modifying ongoing communication practices by establishing a criterion for the timely written confirmation of the initial notification of a nuclear or radiological emergency by the licensee.
11. ADDITIONAL AREAS	**S13**	ENSI should consider ensuring that the interface between safety and security is well documented in its management system to identify potential conflict and ensure that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.

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

List of Acts, Laws and Ordinances related to nuclear energy in Switzerland

Nuclear Energy	
	DETEC Ordinance on the Hazard Assumptions and the Assessment of the Protection against Accidents in Nuclear Installations (SR 732.112.2)
	DETEC Ordinance on the Threat Assumptions and Security Measures for Nuclear Installations and Nuclear Materials (732.112.1)
	DETEC Regulations on the organization, principles and objectives of asset management and on the investment framework of the decommissioning and the disposal fund for nuclear installations (732.179)
	Federal Act on the Swiss Federal Nuclear Safety Inspectorate (ENSIG, 732.2)
	Nuclear Energy Act (NEA, 732.1)
	Nuclear Energy Ordinance (NEO, 732.11)
	Ordinance on Civil Liability in Nuclear Matters (KHV, 732.441)
	Ordinance on Fees of the Swiss Federal Nuclear Safety Inspectorate (ENSI Fee Ordinance, 732.222)
	Ordinance on Personal Security Background Checks in the Area of Nuclear Installations (PSPVK, 732.143.3)
	Ordinance on the Decommissioning and the Waste Disposal Fund for Nuclear Installations (SEFV, 732.17)
	Ordinance on the Federal Nuclear Safety Commission (NSC Ordinance, 732.16)
	Ordinance on the Methodology and Boundary Conditions for the Evaluation of the Criteria for the Provisional Removal from Service of Nuclear Power Plants (732.114.5)
	Ordinance on the Requirements for the Personnel of Nuclear Installations (VAPK, 732.143.1)
	Ordinance on the Security Guards of Nuclear Installations (VBWK, 732.143.2)
	Ordinance on the Swiss Federal Nuclear Safety Inspectorate (ENSIV, 732.21)
	Ordinance on Vessels and Piping classified as important to safety in Nuclear Installations (OVPN, 732.13)
	Personnel Rules of the Swiss Federal Nuclear Safety Inspectorate ENSI (ENSI Personnel Rules, 732.221)

Radiation Protection	
	Ordinance on Dosimetry (OD, 814.501.43)
	Ordinance on Fees relating to Radiological Protection (Fee-RP, 814.56)
	Ordinance on Measuring Equipment for Ionising Radiation (StMmV, 941.210.5)
	Ordinance on Radiation Protection of Radiation Generators (ORPRG, 814.501.51)
	Ordinance on Radiological Protection for Medical X-Ray Systems (RöV, 814.542.1)

	Ordinance on Radiological Protection in medical particle accelerator facilities (BeV, 814.501.513)
	Ordinance on the Handling of Radioactive Materials (HRMO, 814.554)
	Ordinance on the Handling of Sealed Radioactive Sources in Medicine (MeQV, 814.501.512)
	Ordinance on the Supply of the Population with Iodine Tablets (Iodine Tablets Ordinance, 814.52)
	Ordinance on the Training and Continuing Education and the Permitted Activities in Radiological Protection (RPTO, 814.501.261)
	Radiological Protection Act (RPA, 814.50)
	Radiological Protection Ordinance (RPO, 814.501)

Emergency Preparedness	
	Ordinance on Civil Protection (OCP, 520.12)
	Ordinance on the Protection in the Case of an Emergency (OPCE, 732.33)
	Ordinance on the Federal Civil Protection Crisis Management Board (VBSTB, 520.17)

Miscellaneous	
	Federal Act on Administrative Procedure (Administrative Procedure Act, APA, 172.021)
	Federal Act on Freedom of Information in the Administration (Freedom of Information Act, FoIA, 152.3)
	Federal Act on the Consultation Procedure (Consultation Procedure Act, CPA, 172.061)
	Federal Act on the Personnel of the Swiss Confederation (FPA, 172.220.1)
	Federal Constitution of the Swiss Confederation (Cst, 101)
	Government and Administration Organisation Act (GAOA, 172.010)
	Ordinance on Freedom of Information in the Administration (Freedom of Information Ordinance, FoIO, 152.31)
8	Federal Ordinance on the Personnel of the Swiss Confederation (FPersO, 172.220.111.3)
9	Federal Act on Data Protection (FADP, 235.1)
10	Ordinance on the Protection of Federal Information (Information Protection Ordinance, IPO, 510.411)
11	Ordinance on the National Emergency Operation Centre (NEOC Ordinance, 520.18)
12	Compulsory Purchase Act (ComPurA, 711)
13	Ordinance on Fees and Supervision Charges in the Energy Sector (FeeO-EnS, 730.05)
14	Ordinance on the Transportation of Dangerous Goods by Road (741.621)

15	Ordinance on Hazardous Materials Officers for the Transportation of Dangerous Goods by Road, Rail, and Water (741.662)
16	Ordinance on the Transportation of Dangerous Goods by Rail and Cableways (742.412)
17	Federal Act on the Protection of the Environment (Environmental Protection Act, EPA, 814.01)
18	Protection against Major Accidents Ordinance (MAO, 814.012)
19	FDHA Ordinance on Maximum Levels of Contaminants (VHK, 817.022.15)
20	Federal Act on Accident Insurance (AIA, 832.20)
21	Swiss Federal Ordinance on the Prevention of Accidents and Occupational Diseases (OPAOD, 832.30)
22	Measuring Instruments Ordinance (MIO, 941.210)
23	Federal Act on the Control of Dual-Use Goods, Specific Military Goods and Strategic Goods (Goods Control Act, GCA, 946.202)
24	Ordinance on the Export, Import and Transit of Dual Use Goods, Specific Military Goods and Strategic Goods (Goods Control Ordinance, GCO, 946.202.1)
25	European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR, 0.741.621)
26	Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention, 0.814.07)

List of ENSI's regulatory documents (Guidelines) per May 2021

Guideline	Year	Title
Series A: Guidelines covering the assessment of facilities		
ENSI-A01	2018/20	Technical Safety Analysis for Existing Nuclear Installations: Scope, Methodology and Boundary Conditions
ENSI-A03	2014/18	Periodic Safety Review for Nuclear Power Plants
ENSI-A04	2008/2009/2016	Application Documents for Modifications to Nuclear Installations Requiring a Permit
ENSI-A05	2018	Probabilistic Safety Analysis (PSA): Quality and Scope
ENSI-A06	2015	Probabilistic Safety Analysis (PSA): Applications
ENSI-A08	2010	Source Term Analysis: Scope, Methodology and Boundary Conditions
Series B: Guidelines covering the surveillance of operations;		
ENSI-B01	2011	Ageing Management
ENSI-B02	2015/2021	Periodic Reporting by the Nuclear Installations
ENSI-B03	2016	Reports by the Nuclear Installations

ENSI-B03	*under revision: draft published for public hearing*	*Reports by the Nuclear Installations*
ENSI-B04	2018	Clearance of Controlled and Supervised Areas and of Materials from Mandatory Licensing and Supervision
ENSI-B05	2007/2018	Requirements for the Conditioning of Radioactive Waste
ENSI-B06	2013	Safety Classified Vessels and pipework: Maintenance
ENSI-B07	2008	Vessels and Piping Classified as Important to Safety: Qualification of Non-Destructive Testing
ENSI-B08	*draft published for public hearing*	*Vessels and Piping Classified as Important to Safety: Periodic Inspections*
ENSI-B09	2018	Determination and Recording of the Doses of Persons Exposed to Radiation
ENSI-B10	2010	Basic Training, Recurrent Training and Continuing Education of Personnel in Nuclear Installations
ENSI-B11	2007/2013/ 2020	Emergency Exercises
ENSI-B12	2019	Emergency Preparedness in Nuclear Installations
ENSI-B13	2010	Training and Continuing Education of the Radiation Protection Personnel
ENSI-B14	2010	Maintenance of Electrical and Instrumentation and Control Equipment Classified as Important to Safety
ENSI-B17	2020	Operation of Interim Storage Facilities for Radioactive Waste
Series G: Guidelines with general requirements *(covering both the assessment of facilities and surveillance of operations).*		
ENSI-G01	2011	Safety Classification for Existing Nuclear Power Plants
ENSI-G02	2019	Design Principles for Operational Nuclear Power Plants
ENSI-G03	2020	Deep Geological Repositories
ENSI-G05	2008	Transport and Storage Casks for Interim Storage
ENSI-G05	*under revision: draft published for public hearing*	*Transport and Storage Casks for Interim storage: Design and Manufacturing*
ENSI-G07	2013	The Organisation of Nuclear Installations
ENSI-G08	2015	Systematic Safety Assessments for the Operation of Nuclear Installations

Guideline	Year	Title
ENSI-G09	2014/2019	Operational Documentation
ENSI-G11	2013	Safety classified vessels and pipework: Engineering, manufacture and installation
ENSI-G12	*draft published for public hearing*	*Radiation Protection in Nuclear Installations*
ENSI-G13	2015/2018	Measuring Instrumentation for Ionising Radiation
ENSI-G14	2009	Calculation of Radiation Exposure in the Vicinity due to Emission of Radioactive Substances from Nuclear Installations
ENSI-G15	2010	Radiation Protection Objectives for Nuclear Installations
ENSI-G17	2014	Decommissioning of Nuclear Installations
ENSI-G20	2015	Reactor Core, Fuel Assemblies and Control Rods: Design and Operation
ENSI-G23	*draft published for public hearing*	*Design Principles for other Nuclear Facilities*
Other regulatory bases		
HSK-R07	1995	Guideline for the Radiological Monitored Area of the Nuclear Installations and the Paul Scherrer Institute
HSK-R08	1976	Safety of structures for nuclear installations, federal test procedures for the construction of structures
HSK-R46	2005	Requirements for the Application of Computer-Based Instrumentation and Control Important to Safety in Nuclear Power Plants
HSK-R50	2003	Requirements Important to Safety for Fire Protection in Nuclear Installations (will be replaced by ENSI-G18, draft ready for internal hearings)
HSK-R102	1986	Design criteria for the protection of safety-relevant equipment in nuclear power plants against the consequences of aircraft crashes

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006)

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSG-2, IAEA, Vienna (2011).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Communication and Consultation with Interested Parties by the Regulatory Body, IAEA Safety Standards Series No. GSG-6, IAEA, Vienna (2017)

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018)

[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (2018).

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Arrangements for Preparedness for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GS-G-2.1, IAEA, Vienna (2007).

[12] ATOMIC ENERGY AGENCY, INTERNATIONAL CIVIL AVIATION ORGANIZATION, Arrangements for the Termination of a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSG-11, IAEA, Vienna (2017).

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Occupational Radiation Protection, IAEA Safety Standards Series No. GSG-7, IAEA, Vienna (2018).

[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing the Infrastructure for Radiation Safety, IAEA Safety Standards Series No. SSG-44, IAEA, Vienna (2018)

[15] INTERNATIONAL ATOMIC ENERGY AGENCY, WORLD HEALTH ORGANIZATION, PAN AMERICAN HEALTH ORGANIZATION AND INTERNATIONAL LABOUR OFFICE, Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Safety Standards Series No. SSG-46, IAEA, Vienna (2018)

[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Environmental and Source Monitoring for Purposes of Radiation Protection, IAEA Safety Standards Series RS-G-1.8, IAEA, Vienna (2005)

[17] INTERNATIONAL ATOMIC ENERGY AGENCY, Categorization of Radioactive Sources, IAEA Safety Standards Series No. RS-G-1.9, IAEA, Vienna (2005)

[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Control of Radioactive Discharges to the Environment, IAEA Safety Standards Series No. GSG-9, IAEA, Vienna (2018).

[19] INTERNATIONAL ATOMIC ENERGY AGENCY, Code of Conduct on the Safety and Security of Radioactive Sources, IAEA/CODEOC/2004, IAEA, Vienna (2004).

[20] INTERNATIONAL ATOMIC ENERGY AGENCY, Guidance on the Import and Export of Radioactive Sources, IAEA, Vienna (2012).

[21] INTERNATIONAL ATOMIC ENERGY AGENCY, Guidance on the Management of Disused Radioactive Sources, IAEA, Vienna (2018)

[22] INTERNATIONAL ATOMIC ENERGY AGENCY, SARIS Guidelines, IAEA Services Series No. 27, IAEA, Vienna (2014).

APPENDIX VIII – ORGANIZATIONAL CHART